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THE IMPACT OF THE CARDIAC NURSE SPECIALIST IN
IMPLEMENTING CORONARY HEART DISEASE MANAGEMENT
IN PRIMARY CARE

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This thesis is presented for Master of Science Degree (by Research)

Nursing & Midwifery School
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ABSTRACT

Introduction: Coronary heart disease (CHD) is the major cause of death and disability in the Western society. Much is known about the disease process and its contributing risk factors. This, and evidence from clinical pharmaceutical trials has been used to develop clinical guidelines for best practice. Despite this, the healthcare literature repeatedly demonstrates sub optimal CHD risk factor and medical management of patients. More effective measures of health promotion, care management directed to achieve risk factor targets and education are recommended.

Study aims and objectives: The research has two main aims. First to investigate the extent to which secondary prevention measures for CHD patients are managed in a contemporary West of Scotland setting and, second to evaluate a new healthcare model for the secondary prevention of CHD, with the care to be provided by a cardiac nurse specialist (CNS) working with patients and the healthcare team across the primary and secondary care interface.

The specific objectives of this thesis are:

- To identify the extent to which evidence based practice is applied to the management of patients with CHD.
- To examine the perceived health status of CHD patients and their motivation to make healthy lifestyle changes.
- To evaluate the impact of a CNS in the management of patients with CHD.

Patients and Study Design:

The study was undertaken in two phases. The CNS, in partnership with the primary care team, undertook both phases of the research. Patients (n=531) in phase I (part A) were identified using computerised database disease registers. The collection of data consisted of a retrospective casenote review of the presence of coronary risk factors and appropriate evidence based medical treatments. Following casenote review, patients (n=475), a sub group of phase I (part A), were identified for their suitability to participate in phase I (part B), a prospective observational study. Patients were sent a postal questionnaire which examined both the perceived health status of patients with CHD, and, the presence of current coronary risk factors. The postal questionnaire also identified those indicating motivation to make healthy lifestyle changes. In phase II, a subset of motivated patients from the original cohort of phase I patients, were recruited to a randomised control trial (RCT) (n=91). The RCT was designed to evaluate the impact of a new care model. The intervention group (n=45) were recruited to a new nurse-led intervention, versus, the control group (n=46), who were assigned to usual care from their GP practice team.

Results

Phase I – Part A

The analysis from the retrospective casenote review identified the following percentage of patients who had documentation of the main CHD risk factors recorded within the previous 12 months:

- Blood pressure 40%, weight 59.5% and cholesterol 62% were recorded in patients casenotes over a 12 month period.
- Smoking status, ever recorded, was available in 98% of patients casenotes, with a documented 23.5% current smokers

- Aspirin 77.5%, beta blockers (post MI) 46% and statin 56% were recorded in casenotes as being prescribed

Phase I – Part B

The postal questionnaire achieved the following results:

- 76% of patients responded, with the majority (66%) indicating motivation to make healthy lifestyle changes
- Patients were well informed of their past and present medical history and had received or obtained relevant education about their health

Phase II

- Baseline levels for cholesterol, blood pressure, smoking, BMI, SF36 and prophylactic medication were similar with no statistically significant difference

At 12 months:

- There was a significant difference in the changes in cholesterol between the intervention group (0.74mmol/l) and control group (0.19mmol/l) $p=0.018$.
- The percentage of patients with a target cholesterol ($\leq 5.0\text{mmol/l}$) was 79% in the intervention group versus 45% in the control group ($p=0.002$).
- At 12 months there was a significant difference in the changes in systolic blood pressure between the intervention group (17.97mmHg) and control group (5.43mmHg) $p=0.009$. Similarly at 12 months there was a significant difference in the changes in diastolic blood pressure between the intervention group (13.13mmHg) versus control group (6.36mmHg) $p=0.006$
- The percentage of patients with a target blood pressure ($\leq 140/85\text{mmHg}$) was 97% in the intervention group versus 61% in the control group for the same period ($p=0.000$).

- At 12 months there was no significant difference observed between the groups for the number of patients achieving smoking cessation ($p=0.519$). However the total number of cigarettes smoked by patients was significantly reduced in the intervention group compared to control group ($p=0.004$).
- At 12 months a greater percentage of patients within the intervention group (42%) reached target body mass index (BMI) versus control group (19%) ($p=0.025$).
- Some improvements within the intervention group were made to quality of life, as measured by the Short form 36 questionnaire, however these were not statistically significant.
- At 12 months differences in prescribing of Aspirin 95% versus 93% ($p>0.5$), Statin 87% versus 71% ($p=0.092$) ACE inhibitor 42% versus 14% ($p=0.005$) and Beta blocker 47% versus 50% ($p>0.5$), intervention versus control respectively were observed.

Conclusion: Sub-optimal risk factor documentation and management of patients with CHD continues to exist in current practice. The CNS significantly improved outcomes in secondary prevention management of motivated patients with CHD. Further research may wish to examine whether this model of care can be effective in patient groups considered to be poorly motivated with higher levels of risk factors present. This thesis has proved that this model of care is effective in improving risk factor modification in a group most likely to benefit from such intervention. In addition to this, the new model of care demonstrates a structured comprehensive care pathway, which could be reproducible.

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be on the “To do” list. And finally, my children Ethan and Noah, who I love dearly, without them I would have completed this thesis a long time ago!

I would like to dedicate this thesis to my parents, Jim and Sheena.

Declaration

The work presented in this thesis was performed solely by the author, except where the assistance of others is acknowledged.

List of contents

1.0 INTRODUCTION.....	1
1.1 Burden of Coronary Heart Disease.....	1
1.2 CHD risk factors and management.....	1
1.3 The changing face of Primary Care	3
1.4 The role of Nurse Specialist.....	3
1.5 Purpose and rationale of the research	4
1.6 Layout of the thesis.....	4
2.0 LITERATURE REVIEW	5
2.1 Search Parameters	5
2.2 Introduction.....	5
2.3 Epidemiology of coronary heart disease.....	6
2.3.1 Worldwide.....	6
2.3.2 United Kingdom (UK)	7
2.3.3 Scotland.....	8
2.3.4 Glasgow	8
2.4 Pathophysiology of Coronary Heart Disease.....	9
2.4.1 Coronary Atherosclerosis.....	9
2.4.2 Myocardial ischaemia	10
2.4.3 Manifestations of myocardial ischaemia	10
2.4.4 Angina.....	11
2.4.5 Myocardial infarction (MI)/Acute Coronary Syndrome.....	11
2.5 Coronary Risk Factors	13
2.5.1 Smoking	13
2.5.2 Diabetes.....	16
2.5.3 Hypertension	16
2.5.4 Hypercholesterolaemia	18
2.5.5 Obesity	21
2.5.6 Inactivity	22
2.5.7 Alcohol.....	23
2.5.8 Extent to which risk factors and intervention impact on CHD mortality	24
2.6 Management of patients with CHD	25
2.6.1 Joint British Guidelines.....	25
2.6.2 Scottish Intercollegiate Guidelines Network (SIGN).....	27
2.6.3 National Service Framework (NSF).....	27

2.7 Overview of current practice	28
2.7.1 Surveys of secondary prevention management	29
2.8 Prophylactic medication.....	31
2.8.1 Antiplatelet therapy	31
2.8.2 Beta adrenergic blocking agents (β blockers)	33
2.8.3 Statins.....	34
2.8.4 Angiotensin Converting Enzyme Inhibitors	34
2.9 Implementation of prophylactic medications	36
2.10 Quality of Life (QOL).....	36
2.11 Behavioural change	40
2.11.1 Motivational interviewing.....	40
2.12 Nurse-led Intervention.....	41
2.12.1 Introduction	41
2.12.2 Advanced nursing roles.....	42
2.12.3 Nurse Consultants	43
2.12.4 Cardiac Nurse Specialist Roles	43
2.13 Conclusion.....	48
 3.0 LITERATURE PERTAINING TO METHODS.....	 50
3.1 Introduction.....	50
3.2 Research Design.....	50
3.3 Ethical considerations	51
3.4 Subject recruitment and consent	52
3.5 Randomisation.....	53
3.6 Randomised Control Trials.....	54
3.7 Data collection methods	54
3.7.1 Reliability and Validity.....	54
3.7.2 Retrospective and Prospective Data	55
3.7.3 Quantitative and Qualitative Research	56
3.8 Introduction to Data Collection Tools	57
3.8.1 Questionnaires	57
3.8.2 Postal questionnaires	58
3.8.3 Interview Schedules.....	59
3.9 Construction of questions.....	59
3.9.1 Open questions	60
3.9.2 Closed questions.....	60

3.9.3 Rating scales.....	61
3.10 Pre validated research tools	63
3.10.1 Introduction.....	63
3.10.2 Short form 36 (SF36).....	63
4.0 MATERIALS AND METHODS.....	65
4.1 Introduction.....	65
4.2 Study Aims.....	65
4.3 Study objectives.....	65
4.4 Research Questions	66
4.5 Study Design	66
4.6 Sample Source	67
4.7 Subject Number.....	68
4.8 Sampling Procedure	69
4.8.1 Inclusion criteria.....	69
4.8.2 Exclusion criteria.....	69
4.9 Research Setting.....	70
4.10 Ethical Consideration.....	71
4.11 Informed Consent.....	71
4.12 Phase I – Preparation of data collection tools	72
4.13 Phase I – part A	72
4.13.1 Proforma.....	72
4.13.2 Pilot phase I – part A	73
4.13.3 Evaluation of pilot phase I – part A.....	73
4.14 Phase I – part B	74
4.14.1 Postal Questionnaire	74
4.14.2 Pilot Phase I – part B	74
4.14.3 Evaluation of pilot Phase I – part B.....	74
4.15 Phase I – Main Study.....	76
4.15.1 Administration of Proforma	76
4.15.2 Administration of Postal Questionnaire.....	77
4.16 Phase II – preparation of data collection tools	77
4.16.1 Pilot of Phase II data collection tools	78
4.16.2 Changes to Interview Schedule following pilot	78

4.17 Pilot study of intervention.....	78
4.17.1 Evaluation of intervention method following pilot study	79
4.18 Phase II Main study.....	80
4.18.1 Baseline Visit	80
4.18.2 Clinical Measures	82
4.18.3 Blood Pressure.....	82
4.18.4 Body Mass Index	82
4.18.5 Venous blood sampling.....	83
4.18.6 Randomisation for phase II	84
4.19 Intervention group.....	84
4.20 Control group	86
4.21 Data Management and Analysis	87
4.21.1 Phase I.....	87
4.21.2 Phase II.....	87
4.22 Data Analysis	88
4.22.1 Variables	88
4.22.2 Summary Statistics	88
4.22.3 Normal distribution.....	90
4.22.4 Hypothesis.....	90
4.22.5 Intention to Treat	91
4.22.6 Presentation of results	91
 5.0 RESULTS – PHASE I	 93
5.1 Introduction.....	93
5.2 Patient selection	94
5.2.1 Age and gender.....	95
5.3 Past Medical History	95
5.4 Risk factors	96
5.5 Prophylactic evidence based medication	98
5.6 Part B.....	99
5.7 Patient selection	99
5.8 Questionnaire responses.....	101
5.9 Medication	102
5.10 Perceptions of general health and fitness.....	102
5.11 Motivation to change.....	103

5.12 Education	105
5.13 Conclusion	106
6.0 RESULTS – PHASE II	107
6.1 Introduction.....	107
6.2 Patient selection	107
6.3 Questionnaire A response rate.....	108
6.4 Patient selection	109
6.5 Summary of baseline characteristics for randomised control trial	111
6.6 Follow up of patients	113
6.7 Changes from baseline to 12months	114
6.8 Percentage of patients reaching target levels in accordance with current guidelines	116
6.9 Prophylactic evidence based medication	118
6.10 Short Form 36 health survey (SF-36)	121
6.12 Analysis by Intention to Treat	124
6.13 Trends in risk factors over 12 months for the intervention group only	125
6.13.1 Blood pressure	125
6.13.2 Body mass index (BMI).....	127
6.13.3 Cholesterol	128
6.14 Conclusion	129
CHAPTER 7.0 DISCUSSION	130
7.1 Introduction.....	130
7.2 Research Aims and Questions.....	130
7.3 Answering the research questions.....	131
7.4 Observed levels of coronary risk factor documentation in medical casenotes for those patients with known CHD	131
7.5 To what extent are patients with CHD managed in relation to reaching recommended target levels for coronary risk factors?	133
7.6 Prescribing trends for the implementation of evidence based prophylactic medication in patients with CHD	135

7.7 Sub optimal management does not appear to affect patients perceptions of general health	136
7.8 Patient motivation to make healthy lifestyle changes.....	137
7.9 The impact of the CNS in improving and managing CHD in those patients motivated to make healthy lifestyle changes	138
7.10 Study limitations.....	143
7.11 Recommendation for further research	144
7.12 General conclusions	145
7.13 Full Circle	146
Appendix I: Coronary event rates per country from the WHO MONICA Project for (a) men and (b) women.....	161
Appendix II: ABCD to hypertension.....	163
Appendix III: Body Mass Index Calculation	165
Appendix IV: Proposal for Ethical Approval	167
Appendix V: Proforma.....	174
Appendix VI: GP consent forms for contacting patient by postal questionnaire	178
Appendix VII: Postal questionnaire	180
Appendix VIII: Interview Schedule.....	188
Appendix IX: Patient held record cards	197
Appendix X: Abstract accepted for poster presentation at the European Society of Cardiology 2000, Amsterdam, The Netherlands 26-30 August 2000.....	199
Appendix XI: Professional Nurse: Nurse-led interventions contribute to cutting the risks for heart disease.....	201

List of tables

TABLE 1 TREATMENT TARGETS FOR MODIFIABLE RISK FACTORS26

TABLE 2 TIME PLAN OF STUDY67

TABLE 3 NUMBERS IDENTIFIED BY MEANS OF POWER CALCULATION FOR RCT68

TABLE 4 SUMMARY STATISTICS FOR MODIFIABLE RISK FACTORS PHASE I PART A97

TABLE 5 POSTAL QUESTIONNAIRE RESPONSE IN ACTUAL NUMBERS.....109

TABLE 6 CONTROL AND INTERVENTION GROUPS AT BASELINE111

TABLE 7 BASELINE CHARACTERISTICS FOR INTERVENTION AND CONTROL IN RELATION TO
RISK FACTOR TARGETS AND PRESCRIBING.....112

TABLE 8 BREAKDOWN OF % OF PATIENTS DOCUMENTED IN BOTH GROUPS WITH ONE OR
MORE IHD DIAGNOSIS113

TABLE 9 ILLUSTRATES THE CHANGES FOUND BETWEEN THE TWO GROUPS AT 12 MONTHS115

TABLE 10 DEMONSTRATES STATISTICAL SIGNIFICANCE FOUND BETWEEN GROUPS AT 0 AND
12 MONTHS118

TABLE 11 CHANGES FOUND IN PRESCRIBING BETWEEN THE TWO GROUPS AT BASELINE AND
12 MONTH FOLLOW UP121

TABLE 12 MEAN (SD) SHORT FORM 36 HEALTH SURVEY (SF-36) SCORES AT BASELINE AND
12 MONTHS AND MEAN CHANGES IN SCORES BETWEEN BASELINE AND 12 MONTHS IN
INTERVENTION AND CONTROL GROUPS122

TABLE 13 TRENDS IN ALCOHOL CONSUMPTION OVER THE STUDY PERIOD - FIGURES ARE
PRESENTED IN ACTUAL NUMBERS.....123

TABLE 14 SUMMARY OF RESULTS OF TWO SAMPLE T-TESTS (USING ANALYSIS BY INTENTION
TO TREAT)124

List of figures

FIGURE 1 METHODS EMPLOYED IN THE IDENTIFICATION AND SELECTION OF PATIENT NUMBERS FOR PHASE I - PART A	94
FIGURE 2 PERCENTAGE OF PATIENTS WITH DOCUMENTATION OF ONE OR MORE IHD DIAGNOSIS, AS RETRIEVED FROM CASENOTE ANALYSIS	95
FIGURE 3 COMPARISON OF THE % OF PATIENTS FOUND IN ASPIRE AND IN THE CURRENT STUDY WITH DOCUMENTATION OR CORONARY RISK FACTORS.....	96
FIGURE 4 METHODS EMPLOYED IN IDENTIFICATION AND SELECTION OF PATIENT NUMBERS FOR PHASE I - PART B.....	100
FIGURE 5 COMPARISON OF PATIENT % WITH DOCUMENTATION OF DIAGNOSIS IN CASENOTE RETRIEVAL VERSUS PATIENT'S OWN REPORTING IN POSTAL QUESTIONNAIRE	102
FIGURE 6 DISTRIBUTIONS OF RESPONSES OF PATIENTS PERCEPTIONS OF LEVEL OF HEALTH, FITNESS AND DIET	103
FIGURE 7 PERCENTAGE OF PATIENTS RESPONDING TO POSTAL QUESTIONNAIRE INDICATING AREAS OF LIFESTYLE THEY WISH TO ADDRESS.....	104
FIGURE 8 ACTUAL NUMBERS OF PATIENTS REPORTING REASONS FOR WISHING TO MAKE LIFESTYLE CHANGES.....	104
FIGURE 9 INDICATES WHERE PATIENTS SOURCE THEIR EDUCATIONAL INFORMATION, DATA ARE PRESENTED AS % AND PATIENTS MAY HAVE IDENTIFIED MORE THAN ONE AREA	105
FIGURE 10 METHODS EMPLOYED IN IDENTIFICATION AND FOLLOW UP OF PATIENT NUMBERS FOR PHASE II.....	108
FIGURE 11 METHODS EMPLOYED IN THE IDENTIFICATION AND SELECTION OF PATIENT NUMBERS FOR PHASE II - RANDOMISED CONTROL TRIAL.....	110
FIGURE 12 DETAILS OUTCOME OF PATIENTS UNABLE TO COMPLETE 12 MONTH RCT	114
FIGURE 13 PERCENTAGE OF PATIENTS IN BOTH GROUPS REACHING TARGET BLOOD PRESSURE AT 0 AND 12 MONTHS	116
FIGURE 14 PERCENTAGE OF PATIENTS IN BOTH GROUPS REACHING TARGET CHOLESTEROL AT 0 AND 12 MONTHS	117
FIGURE 15 PERCENTAGE OF PATIENTS IN BOTH GROUPS REACHING TARGET BMI AT 0 AND 12 MONTHS	117
FIGURE 16 PERCENTAGE OF PATIENTS PRESCRIBED ASPIRIN AT 0 AND 12 MONTHS	119

FIGURE 17 PERCENTAGE OF PATIENTS PRESCRIBED BETA BLOCKER AT 0 AND 12 MONTHS	119
FIGURE 18 PERCENTAGE OF PATIENTS PRESCRIBED STATIN AT 0 AND 12 MONTHS.....	119
FIGURE 19 PERCENTAGE OF PATIENTS PRESCRIBED ACE INHIBITOR AT 0 AND 12 MONTHS	120
FIGURE 20 PRESENTS THE MEAN RECORDING OF SYSTOLIC BLOOD PRESSURE (SBP) IN THE INTERVENTION GROUP AT 3, 6, 9 AND 12 MONTHS	125
FIGURE 21 PRESENTS THE MEAN RECORDING OF DIASTOLIC BLOOD PRESSURE (DBP) IN THE INTERVENTION GROUP AT 3, 6, 9 AND 12 MONTHS	126
FIGURE 22 PRESENTS THE MEAN RECORDING OF BODY MASS INDEX (BMI) IN THE INTERVENTION GROUP AT 3, 6, 9 AND 12 MONTHS	127
FIGURE 23 PRESENTS THE MEAN RECORDING OF TOTAL CHOLESTEROL IN THE INTERVENTION GROUP AT 3, 6, 9 AND 12 MONTHS.....	128

1.0 Introduction

1.1 Burden of Coronary Heart Disease

The incidence of Coronary Heart Disease (CHD) in the United Kingdom (UK) accounts for approximately 268,000 new cases of myocardial infarction (MI) and 338,000 new cases of angina each year. Further, the most recent CHD statistics from the British Heart Foundation (BHF) estimate the prevalence to be around 2.6million people (British Heart Foundation 2005).

Epidemiological evidence has observed a fall in the mortality from CHD, which may be attributed to a greater understanding of the disease and advances in medical therapy. However, CHD remains the UKs leading cause of death, responsible for in excess of 110,000 lives in 2003. In Scotland alone, the rate of premature death from CHD was reported to be 84% higher than that found in the south west of England (BHF 2005). A distinct north to south divide is known to exist within the UK, but it would appear from epidemiological work that the gap is widening.

1.2 CHD risk factors and management

CHD is a multifactorial disease. Evidence from large epidemiological studies such as the Framingham Study (Woodbury, *et al* 1979) have improved our understanding of coronary risk factors and their relationship to coronary event rates. Several modifiable risk factors have been identified. Risk factors such as hypertension, hypercholesterolaemia and diabetes once established and identified can be treated with a combination of lifestyle changes and medical therapy. Other modifiable risk factors include smoking, poor diet, inactivity and excess alcohol (Lindsay 1997).

In addition to addressing lifestyle issues, medical therapy is an important factor in the management of CHD. Landmark clinical pharmaceutical trials, for example the Scandinavian Simvastatin Survival Study (4S) (Scandinavian Simvastatin Survival Study Group 1994) and the First International Study of Infarct Survival (ISIS 1) (First International Study of Infarct Survival Collaborative Group 1986) have clearly demonstrated the positive impact that the initiation of the appropriate evidence based medication can have on outcomes.

Guidelines outlining the evidence base for best practice in CHD management are widely accessible within both primary and secondary care, yet surveys continue to report sub optimal management (Aspire Steering Group 1996; Brady, *et al* 2001). It is likely that a combination of patient motivation and the model of care delivery may be responsible for this.

It cannot be overlooked that patients themselves have a large role to play in the management of CHD, and should be encouraged to share this responsibility with their healthcare team. Making appropriate lifestyle changes to address coronary risk factors and adhering to recommended medical therapy has been shown to significantly improve not only coronary event rates but all vascular event rates (British Cardiac Society 1998; Tunstall-Pedoe *et al.* 1994).

Issues surrounding patient motivation to change have been examined. Motivational interviewing (Prochaska, *et al* 1992) is a psychological model which has been tested in a variety of areas, and attempts to motivate patients to make positive changes. With regard to CHD management, patients who lack motivation may be less inclined to seek medical advice and attempt lifestyle changes, and as such may be at higher risk of sustaining a coronary event.

1.3 The changing face of Primary Care

In 1999 the Scottish Executive, following on from the Acute Services Review (Scottish Office 1998) published the *"Introduction of Managed Clinical Networks within the NHS in Scotland"* (Scottish Executive 1999). The aims of the Managed Clinical Networks (MCN) are to integrate service provision across primary, secondary and tertiary care. In a similar vein to the Joint British Societies Guidelines (British Cardiac Society *et al.* 2005) in cardiology, the MCN's aim to move away from centers working in isolation and join forces to ensure patients are provided with the best possible care. Highlighted in the report is a recommendation that the MCN concept could prove effective in CHD management. One way of tackling this may be with the establishment of nurse led secondary prevention clinics for management of patients with CHD. Some work has been undertaken in this area examining different models of care (Campbell *et al.* 1998b; Jolly *et al.* 1999).

1.4 The role of Nurse Specialist

A number of nurse specialist and advanced nursing posts exist in the United Kingdom, although little attention has been given to evaluating these roles in terms of clinical effectiveness. Nurse specialist posts exist in almost every area of nursing, within both primary and secondary care, and this has predominantly arisen as a result of changes in junior doctors hours, increased demands on clinical practice and a recognition of unmet health care needs. Within the cardiology setting examples of advanced nursing practice can be seen in both primary and secondary care. First, nurse led thrombolysis significantly improved 'door to needle time' for patients presenting to hospital with myocardial infarction (MI), thus improving survival rates (Armstrong 2003; Potts 2002). Heart failure liaison nurses, which originated from Glasgow have been established throughout the UK with evidence of effectiveness (Bluc *et al.* 2001). Finally, nurse led chest pain

clinics are now widely established for the investigation of patients with suspected cardiac chest pain.

1.5 Purpose and rationale of the research

Taking all of the above factors into consideration, in addition to Glasgows poor coronary heart disease record (Tunstall-Pedoe *et al* 1994), the idea of integrating a cardiac nurse specialist (CNS), with secondary care experience into primary care was conceived. This thesis initially set out to examine how well patients with coronary heart disease were managed in primary care. Once this initial research question was answered the next phase in the research was to explore the impact a specialist cardiac nurse could have in managing patients with coronary heart disease. Exploration of the current literature has suggested the need for better assessment and management of coronary risk factors and evidence based treatment.

1.6 Layout of the thesis

The thesis begins with a review of the current literature in chapter 2 outlining the main research aims. Literature pertaining to the methods employed is discussed in chapter 3, and the materials and methods chosen are detailed in chapter 4. Results from the thesis are presented in two separate chapters. Chapter 5 presents the results for phase I parts A and B, chapter 6 presents the results of the randomised control trial undertaken in phase II. Chapter 7 completes the thesis with a broad discussion of the findings and concludes with the main outcomes of the thesis, discussing implications of the research, study limitations and considerations for the future.

2.0 Literature Review

2.1 Search Parameters

The literature search undertaken for this thesis was commenced in 1998 and updated on a continuous basis. The following databases were searched: MEDLINE (Index Medicus and the International Nursing Index) 1966-March 2006, CINAHL (the Cumulative Index of Nursing and Allied Health Literature) 1982-March 2006, BNI (British Nursing Index) 1985-March 2006 and the Cochrane Database.

Key words and phrases used were coronary heart disease, secondary prevention, risk factors, evidence based medication, prophylactic medication, quality of life, health belief model, and advanced nursing practice. In addition grey literature, computerised databases and a variety of other sources were also reviewed.

2.2 Introduction

Over the last fifteen years more people have died through coronary heart disease (CHD) than any other disease or cause (Mackay & Mensah 2004). This chapter explores what has been described as a "*global epidemic*" (World Health Organisation 2005) and also examines the impact CHD has both internationally and nationally. The chapter discusses the pathophysiology and manifestations of the disease, and examines its contributing factors. In addition, the evolution of advanced nursing roles is described with specific focus given to the role of the Cardiac Nurse Specialist (CNS).

2.3 Epidemiology of coronary heart disease

Data collected from large epidemiological surveys (Potts 2002; Tunstall-Pedoe *et al* 1994; Woodbury, *et al* 1979) over the last few decades has improved our understanding of coronary risk factors. In addition, these data provide useful information on the incidence, prevalence and mortality of CHD.

2.3.1 Worldwide

In 2002 coronary heart disease alone accounted for 7,353,000 deaths in all World Health Organisation (WHO) (World Health Organisation 2005) member states. Data pertaining to worldwide CHD mortality is not available for all populations and in some areas of the world figures are based on crude assumptions (Asplund 2004). What is known from the WHO is that variations from death rates as a result of CHD are striking, with the highest incidence reported in the ex Union of Socialist Soviet Republics (World Health Organisation 2005). In Europe and other countries there appears to be an obvious east to west gradient, however there are also observed inter-country variations. In the example of the UK, a distinct north to south gradient exists. Epidemiology for the UK is discussed below in section 2.2.2.

Over the last few decades trends in CHD morbidity and mortality have fluctuated (World Health Organisation 2005) and there are a number of possible explanations for this. Developing countries tend to adopt a western lifestyle, with increased smoking habits and changes in diet (Kitamura *et al.* 2002). There have also been a number of medical advances over this period, some examples are; the advent of thrombolytic therapy (The GUSTO Investigators 1993), more advanced medical interventions in coronary care units and coronary revascularisation (Channer *et al.*; Guerci & Ross 1989; Hillegass & Brott; The GUSTO Investigators 1993), and implementation of evidence based medical treatment (Goldman & Cook 1984; Tunstall-Pedoe *et al* 1994). As a result, individuals are living longer.

Despite what is known about the disease process and its contributing factors the worldwide burden of CHD is forecast to worsen and further action must be taken (Asplund 2004;Goldman & Cook 1984;Tunstall-Pedoe *et al* 1994;World Health Organisation 2005).

2.3.2 United Kingdom (UK)

In 2003 CHD alone was the most common cause of premature death in the UK population, resulting in just fewer than 114,000 adult deaths (Peterson *et al.* 2005), (appendix I). In the same year CHD was responsible for approximately 38,000 premature deaths in the UK (Peterson , *et al* 2005).

The World Health Organisation (WHO) MONICA project (Tunstall-Pedoe *et al* 1994) published results of a large international epidemiology study. The MONICA project was undertaken over a 10-year period and monitored trends and determinants of approximately 170,000 heart attacks, and risk factors in 35 pre-defined populations across 21 countries. One of the main aims of the research was to identify what factors were responsible for the decline of CHD. One explanation given for the decline in CHD was that event rates were dependent on the driving force behind the disease. For example, in populations where changes to improving lifestyle were made, an expected decline in CHD death would be expected.

Recent statistics published by the British Heart Foundation (BHF) (Peterson *et al* 2005) clearly show that mortality from CHD is declining. Although there is concern that the number of patients with a diagnosis of CHD is rising, this could in part be due to an increasing percentage of people surviving an acute event and an ageing population. It is also important to note that although death rates as a result of CHD in the UK are falling, it would appear to be at a slower rate than in other parts of the world (Asplund 2004). For example, between 1989 and 1999 the death rate in men aged 35-74 years fell by 39%, however in Norway and Australia it fell by 47% (Peterson *et al*

2005). No explanation is given for this but it could be hypothesized that a greater level of health funding in these countries has contributed to these changes.

2.3.3 Scotland

Data observed for the UK indicates a distinct north to south gradient. In Scotland CHD continues to be one of the top three causes of death (General Register Office for Scotland 2005) with 22% of male and 17% of female deaths attributable to CHD in 2003 (Scottish Executive 2005). Death rates in Scotland from CHD are declining and this trend is forecast to continue (Peterson *et al* 2005). *Saving Lives: our healthier nation* (Department of Health 1999), a white paper published in 1999 set a target of a 40% reduction in cardiovascular disease mortality in 2010. This target was not felt to be unrealistic if advances in medical and surgical intervention continue and current trends in coronary risk factors are maintained (Critchley & Capewell 2002). As previously discussed mortality rates have declined in other countries, some at a faster rate than others. Addressing known coronary risk factors has been reported to reduce CHD mortality by as much as 60% to 80% (Capewell, *et al* 1999).

2.3.4 Glasgow

The UK women in the MONICA (Tunstall-Pedoe, *et al* 1994) study were found to have the highest rates of coronary events, with the UK men studied found to have the second highest. The UK site was in fact Glasgow, and as a result a number of health initiatives targeting CHD have been undertaken in Glasgow in an attempt to impact on this. Over the last 5 years Greater Glasgow National Health Service Board (GGNHSB) has been working with both primary and secondary care to tackle the problem of CHD and address a number of key areas, namely coronary risk factors and socio-economic inequalities. In February 1999, the Scottish Executive, Department of Health published a report outlining the introduction of Managed Clinical Networks (MCN) in Scotland (Scottish Executive 1999). The aim of this concept is to integrate care between primary, secondary and tertiary care in an attempt to provide patients with the best evidence based care. Within the Greater Glasgow National Health Service Board (GGNHSB) a

MCN has been established specifically to address CHD. General Practices are being encouraged to establish secondary prevention clinics for the management of patients with CHD.

Surveys have demonstrated that social deprivation plays an important role in the levels of coronary heart disease found around the world (Marmot 2001b; Tunstall-Pedoe *et al* 1994; Yarnell *et al.* 2005). Statistics in Public Health, reporting the level of social deprivation by postcode, are often measured by means of deprivation category scores (DEPCAT) (McLoone 2004). DEPCAT 1 refers to the most affluent areas by postcode and DEPCAT 7, the most deprived. In McLoone's report 30% of the Greater Glasgow National Health Service Board (GGNHSB) population are to be found in DEPCAT 7, this represents 7% of the population of Scotland.

2.4 Pathophysiology of Coronary Heart Disease

Coronary Heart Disease (CHD) can present as angina, myocardial infarction (MI), heart failure or sudden death. The underlying pathophysiology of CHD involves a process called coronary atherosclerosis. The following subsections will describe the process of coronary atherosclerosis.

2.4.1 Coronary Atherosclerosis

Atherosclerosis comes from the Greek "athero" (meaning gruel or paste) and "sclerosis" (hardness). Atherosclerosis is a slow and complex disease process, which post mortem studies has shown to start as early as childhood (Topol *et al.* 2002). It significantly affects the lumen of the coronary arteries and is characterized by the accumulation of lipids and fibrous tissue. This accumulation of materials (known as atherosclerotic plaque) builds up in the inner layer of the coronary artery (endothelium), causing obstructions to varying degrees. These plaques most commonly affect the large and medium-sized coronary arteries and progress as a result of both

age and other contributing factors (Sanderson & Kurth 1983). Due to damage to the endothelium, fats, cholesterol, platelets, cellular waste products, calcium and other substances are deposited in the artery wall (Ross 1999). These cells and surrounding material thicken the endothelium significantly, the coronary artery's diameter narrows and blood flow decreases, reducing oxygen supply. Plaques can grow large enough to significantly reduce the blood's flow through an artery, however most of the damage occurs when they become fragile and rupture (Davies 1987).

2.4.2 Myocardial ischaemia

The oxygen supply to the myocardium is supplied by the coronary arteries and is dependent on a number of haemodynamic factors (Klabunde 2004). The heart unlike other organs in the body demands a greater oxygen supply and for this reason experiences the problems related to coronary artery obstruction. Even at rest the heart extracts a maximum amount of arterial blood supply (Sanderson & Kurth 1983) and as such has little safety margin in its oxygen extraction. For this reason in order for the heart to receive more oxygen it must increase the blood flow to the myocardium, instead of increasing the oxygen extraction. In normal coronary arteries the autonomic nervous system would allow the arteries to dilate therefore increasing oxygen to the myocardium in times of stress. However, changes in the vascular pressure as a result of atherosclerosis can affect the oxygen supply to the myocardium (Klabunde 2004). The arteries have less ability to dilate and are therefore unable to meet the demands of the myocardium. This insufficiency results in what is known as myocardial ischaemia (Crossman 2004).

2.4.3 Manifestations of myocardial ischaemia

The symptoms of myocardial ischaemia vary between individuals, and the term angina is used as an umbrella term to describe one or more symptoms. Angina was historically first recorded in 1768, and was described by an English physician in a lecture to the College of Physicians of

London (Heberden 1802). Angina can be described as stable or unstable and can present in a number of ways.

2.4.4 Angina

Classically, patients may complain of central chest discomfort, with possible radiation to their left arm and associated shortness of breath (Jackson 2000). In stable angina the symptoms occur as a result of coronary ischaemia and will tend to be related to exertion, however, anything, which potentially increases the oxygen demand to the myocardium, may result in symptoms (Crossman 2004). Other symptoms of ischaemia exist and include right arm discomfort, jaw discomfort, sweating and nausea, however these are usually accompanied with one or more of the main presenting features (Jackson 2000).

Unstable angina (UA) is an indication of atheromatous plaque instability and patients should be admitted to hospital for monitoring and treatment as there is concern over plaque fissuring and embolism (Wallentin *et al* 2004). Patients with unstable angina may experience symptoms at rest or with very little exertion and often symptoms are increased in both frequency and severity (Jackson 2000).

2.4.5 Myocardial infarction (MI)/Acute Coronary Syndrome

Rupture of an unstable atheromatous plaque reveals the lipid rich core, which encourages thrombin formation leading to partial or complete occlusion of the coronary artery (Ross 1999). This rupture of the plaque leads to myocardial ischaemia and where myocardial necrosis occurs, this is commonly referred to as myocardial infarction (MI). With the introduction of newer biochemical markers, such as, cardiac Troponins, it has become increasingly more difficult to determine MI from an unstable coronary event (Jaffe *et al* 2004) and as such newer classifications of MI have been formulated.

Cardiac chest pain is now differentiated as stable angina and Acute Coronary Syndromes (ACS) (Pollack, *et al.*; Roe *et al.* 2005; Wallentin *et al.* 2004). Under the umbrella term of ACS are Non ST Elevation Myocardial Infarction (NSTEMI) and ST elevation Myocardial Infarction (STEMI). In both circumstances plaque rupture occurs, however the main difference is whether thrombi result in partial or total occlusion of the artery.

Non ST elevation MI

Patients presenting with NSTEMI tend to have a 'grumbling' course of pain with an increase in frequency and severity of a symptoms over a matter of days to hours, this is due to the partial occlusion of thrombi. Presentation in NSTEMI involves no ST elevation on the electrocardiogram (ECG), symptoms, myocardial necrosis (damage) can occur, however this tends to be less and is often not at a level detectable by standard cardiac markers, such as creatine kinase (CK).

Risk stratification for this group of patients is important. Patients considered to be at higher risk include those with previous MI, diabetes, those requiring urgent coronary revascularisation, heart failure and hypotension (Boersma *et al.* 2000). For those patients deemed at higher risk there is an increased mortality rate of as much as 9% (Antman *et al.* 1996) and a combined rate of death, MI or revascularisation of 40.9% (Altman 2002).

ST elevation MI

Patients presenting with STEMI tend to have a more sudden onset of pain, due to the occlusion of thrombi. As a result of this, STEMI involves ST elevation on the electrocardiogram, symptoms, myocardial damage and resultant cardiac enzyme rise.

Patients sustaining either a STEMI or NSTEMI should ideally be managed in hospital and should be offered a cardiac rehabilitation programme in addition to their medical treatment.

2.5 Coronary Risk Factors

Evidence from laboratory, clinical and epidemiological research has led to major advances in the understanding and pathogenesis of atherosclerosis and its major clinical manifestations, CHD. A number of modifiable risk factors relating to the progression of coronary atherosclerosis and the risk of clinical CHD events are known, and reduction of these risk factors has resulted in a commensurate reduction in non-fatal and fatal CHD and an increase in life expectancy (British Cardiac Society 1998). Thus, there is considerable potential for prevention of CHD. The main modifiable risk factors are smoking, diabetes, hypertension, hypercholesterolaemia, obesity, inactivity and excess alcohol (Lindsay 1997; Styles & McIntyre 1997). It is accepted that genetic factors contribute to CHD, however the World Health Organisation reports that 80%-90% of people dying from CHD were found to have one or more risk factor (World Health Organisation 2005). The following subsections will discuss the extent to which the above risk factors contribute to CHD progression and highlight interventions, which could significantly decrease coronary event rates.

2.5.1 Smoking

Amongst the general population, smoking is probably the most commonly associated risk factor for many different diseases. Over the last fifteen to twenty years smoking has been publicised as being detrimental to individuals health. However, it is only really in the last seven years that the government has taken action to change the profile of smoking (Department of Health 1998).

Smoking rates in the UK have been falling over the last few decades (Office for National Statistics 2003), however there is concern that the number of young females taking up the habit is

increasing (ASH 2004; Department of Health 1998). Smoking is responsible for in excess of 100,000 preventable deaths in the UK every year (The University of Portsmouth for HAD 2002), with the highest rates in the North, North East and West England and Scotland. This figure has reduced significantly over the last ten years with 120,000 deaths related to smoking reported in 1995 (The Health Education Authority 1997). This reduction in smoking related deaths is thought to be due to the continuous reduction in the percentage of current smokers.

People who smoke (ASH 2004) or who are subjected to secondhand smoke (Chen *et al* 2004, Jamrozik 2005), are at increased risk of smoking related illness, such as, cancer, heart disease and stroke (Doll & Peto 1976). The precise mechanism of the effects of smoking and heart disease are still unclear, however it is reported that smokers have higher levels of fibrinogen, and platelets become 'stickier'. Levels of carbon monoxide, found in tobacco smoke increase the movement of lipoproteins from the blood stream to the vessel walls, contributing to atherosclerosis (Mosca 2004).

In Scotland alone 32% of males and 30% of females were reported to be current smokers in 2001 with 20% of all deaths from CHD attributed to smoking (Peterson *et al* 2005). Targets set out in the governments 'White Paper' *Smoking Kills* (Department of Health 1998), clearly identify key areas of service development to be achieved by 2010. Included in the white paper were proposals to employ specialist NHS smoking cessation services, the introduction of nicotine replacement therapy (NRT) on prescription and a commitment to ban tobacco advertising. In addition, more emphasis was focused on smoke free public areas, which is obviously of current significance with the introduction of the recent smoking ban in Scotland. Despite all the above initiatives a great deal is dependent on the individual's own motivation to stop smoking and this will be discussed further in section 2.10.

In a study examining the long-term effects on mortality of stopping smoking after Unstable Angina (UA) and Myocardial Infarction (MI) (Daly *et al* 1983), 555 men aged 60 and under who had survived a first episode of UA or MI were followed up over 13 years. This study assessed

498 of the original cohort of patients who were alive two years after their initial event. 124 were non-smokers at entry (ex-smokers and never smoked) and 374 were smokers at entry. Those smoking five or more cigarettes for the six months prior to the initial event were defined as smokers and all the others including ex-smokers were defined as non-smokers. The results showed that mortality in those who continued to smoke was significantly higher (82.1%) than in those who stopped smoking (36.9%). In terms of average annual follow up over the 13 year period, those who continued to smoke had a mortality 2.8 times higher than those who stopped ($p < 0.01$). The results also suggested that ceasing to smoke is the single most effective action in management of patients with CHD.

There is evidence to suggest that addressing smoking cessation in hospitalised patients is effective and may result in patients achieving abstinence for longer (Vernon *et al* 1999). This group of patients may be more amenable to the idea due to their current health situation. It is likely that owing to a heightened awareness of ill health and probable restrictions on smoking, it may be easier to undertake the task of quitting.

A number of methods of smoking cessation interventions exist, for example, nicotine replacement therapy (NRT) (Russell 1993), acupuncture (White 2006) and behavioural counselling (Agency for Health Care Policy and Research 1996). The literature would suggest that patients attempting to quit might be more successful if they seek the assistance of one or more smoking cessation intervention (Agency for Health Care Policy and Research 1996). Whether or not the actual interventions are responsible for success is debatable, as perhaps those who seek such methods are in fact more highly motivated individuals willing to try anything in an attempt to achieve their goal.

2.5.2 Diabetes

Diabetes mellitus (DM) affects approximately 2 million people in the UK, of these 1.8 million have type II diabetes (non insulin dependent) (Diabetes UK & All-party Parliamentary Group for Diabetes and supported by the Hansard Society 2005), which represents 3% of the population. Diabetes UK forecast a further one million people within the UK have diabetes, which is currently undiagnosed (Diabetes UK & All-party Parliamentary Group for Diabetes and supported by the Hansard Society 2005). Over the last eight years the incidence of diabetes has risen dramatically with an increase of 400, 000 people, (0.7% of the total population).

In Scotland, it was estimated that 210,000 people had diabetes in the year 2000 (Scottish Intercollegiate Guidelines Network 2001), representing 4% of the Scottish population, indicating that figures in Scotland are indeed higher than the rest of the UK.

Patients with a diagnosis of DM, type I or type II, have a two – three fold increased likelihood of developing CHD (Kanters *et al* 1999). Patients with type II diabetes are more likely to experience macrovascular complications, such as coronary atherosclerosis, although patients with type I diabetes are still at risk (Sweeney & Orchard 2004). Of those patients with diabetes 80% will die from CHD (Barnet & O'Gara 2003) .

Diabetes as with CHD is often a multifactorial disease and addressing known risk factors such as obesity, smoking, and cholesterol may reduce coronary events (British Cardiac Society 1998; Lindsay 1997).

2.5.3 Hypertension

Blood pressure is the result of cardiac output and peripheral resistance (Chalmers *et al* 1999). As the heart beats and the left ventricle contracts and blood empties into the aorta, this is known as the 'systolic' blood pressure and is the maximum pressure. As the left ventricle refills this resting pressure is known as the 'diastolic' blood pressure, blood pressure is measured in mmHg (Watson & Royle 1987). Cardiac output is influenced by a number of factors; heart rate, rhythm, left ventricular function, valvular function, preload and autonomic nervous activity.

The current WHO definition of hypertension is a systolic blood pressure of $\geq 140\text{mmHg}$ and/or a diastolic blood pressure of $\geq 90\text{mmHg}$ (World Health Organisation for the Eastern Mediterranean 2005). This is in fact higher than the targets set out in the Joint British Societies Guidelines (British Cardiac Society, British Hypertension Society, Diabetes, HEART, Primary Care Cardiovascular Society, & Stroke Association. 2005) of $140/85\text{mmHg}$, however the WHO definition is aimed at primary prevention.

The causes of hypertension remain unclear (Mayet & Hughes 2003). In approximately 95% of cases of hypertension the cause is unknown. This is referred to as 'essential' or 'primary' hypertension (Carretero & Oparil 2000). However, it is probable that patients have coexistent risk factors, for example, smoking, obesity. In 'secondary' hypertension a number of causes are thought to contribute to hypertension. Renal and endocrine disorders, medication, pregnancy and coarctation of the aorta are the main documented causes in secondary hypertension (Sinclair *et al* 1987). Elevation of both systolic and diastolic blood pressure is associated with an increased morbidity and mortality, risk of cardiovascular disease and renal dysfunction. It is reported that an increase of blood pressure of only 10mmHg reduces life expectancy. Elevated blood pressure results in the thickening of arteries, with hypertrophied smooth muscle. Larger dilated vessels are unable to cope with the increased pressure. The heart is put under strain and can lead to left ventricular hypertrophy, atrial fibrillation, and angina (Kannel *et al* 1998).

Commonly patients are documented to as having "white coat hypertension". This is normally associated with normotensive patients. Evidence demonstrates that patients attending a clinic will have elevated blood pressure recordings, however during ambulatory recordings at home they are entirely normotensive. The reason for this is thought to be due to a stress response, although this theory is often debated. Some clinicians do not believe that stress affects blood pressure (Jhalani *et al* 2005; Little *et al* 2002). Similarly, some hypertension patients are thought to have "white coat effect". The patient is known to have hypertension, however is normally well controlled when monitored at home. Clinic readings again demonstrate elevated readings (Mansoor *et al*

1996). White coat syndrome is important to keep in mind when managing patients blood pressure. If this is suspected then a 24 hour blood pressure monitor may be of particular use.

Management of hypertension is often suboptimal with many patients being intolerant to treatment and not complying with recommended regimens. Evidence would suggest that suboptimal monotherapy may be partly to blame. In a survey undertaken by Sharma *et al* a reported 60% of patients were found to be on only one antihypertensive medication (Sharma *et al* 2004). In 2004 the British Hypertension Society published an AB/CD treatment algorithm, (appendix II) to improve blood pressure management. Each letter refers to an antihypertensive drug class. By instituting a defined protocol it is hoped that blood pressure will be better controlled and the use of monotherapy will be a thing of the past. As yet, there is no evidence to support whether or not this is being implemented in clinical practice.

Moreover, as with CHD, risk factors should be documented and addressed. Addressing known risk factors such as obesity (Bramlage *et al* 2004), inactivity, excessive salt intake (LAW 1991) and dietary habits (Appel *et al* 1997) can be effective in reducing blood pressure. Adopting lifestyle changes may control blood pressure sufficiently to avoid the commencement of antihypertensive medications. This is perhaps not often reinforced to the patient.

2.5.4 Hypercholesterolaemia

The significance of elevated cholesterol as a risk factor for CHD is now well documented. The mechanisms by which atherosclerotic plaques are formed has been studied for over 150 years. In 1856 a German pathologist, Rudolf Virchow (Virchow 1856) hypothesised a link between cholesterol and lipids in the atherosclerotic process. Many years later (1913), further studies undertaken confirmed this relationship, and observed arteromatous plaque formation in rabbits, which was identical to that identified in human patients (Anitschkow 1913).

Despite this knowledge, little emphasis appeared to be directed in addressing cholesterol as a risk factor for CHD. This could in part be due to limited epidemiological evidence highlighting this as an area of importance. However, in 1970, the 'Seven Countries Study' (Keys 1970) demonstrated that in countries with high incidence of CHD median cholesterol levels were elevated. Conversely, countries with a low median cholesterol level had a lower incidence of CHD.

Studies evaluating the impact of diet on lowering plasma cholesterol concentrations have been undertaken, however, the results appear to be variable. Early dietary trials in the 1960's using reduced fat did not convincingly demonstrate reduction in cardiac events or mortality (Baker *et al* 1963; Green *et al* 1963).

The 'Diet and Reinfarction Trial' (DART) (Burr *et al* 1989), examined changes in fat, fish and fibre intakes on death and myocardial infarction. 2,033 men with a history of MI were randomised into a three-arm study. Men randomised were allocated to receive advice on each of three dietary factors: a reduction in fat intake and an increase in the ratio of polyunsaturated to saturated fat, and increase in fatty fish intake, and an increase in cereal fibre intake. Total cholesterol and HDL cholesterol total were monitored. At six months and at two years patients given dietary fat advice tended to have lower plasma cholesterol levels than the other patients, however the differences were not significant. It is possible that during dietary trials there may be issues with compliance. Patients in the intervention group may not eat exactly what they are advised to eat, while patients in the control groups may spontaneously change to that diet being tested.

Probably the most convincing evidence to support lowering cholesterol has emerged as a result of studies examining the benefits of statins. The publication of landmark trials, such as 4S (Scandinavian Simvastatin Survival Study Group 1994) and LIPID (The Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) Study Group 1998) has radically changed how cholesterol is managed in patients with CHD.

Results from the 4S (Scandinavian Simvastatin Survival Study Group 1994) study demonstrated that lowering cholesterol in patients with CHD improved total and CHD mortality. A total of 4,444 patients aged 35-70 years with Angina or previous Myocardial Infarct (MI) with serum total cholesterol of 5.5 – 8.0mmol/l were studied. The study involving both men and women, was a double-blind randomised control trial was undertaken with patients receiving either Simvastatin or placebo. Patients were stratified for location and previous MI. Groups were well matched for age, sex and CHD risk factors. This study demonstrated in a large number not only a reduction in cardiovascular mortality (8% in Simvastatin group versus 12% in placebo group, ($p= 0.0003$) but also a non statistically significant difference in non cardiac mortality, disproving previous concerns about the safety of Statin therapy. Over the five-year follow up Simvastatin reduced total cholesterol by 25%.

In 1989 the Long-Term Intervention with Pravastatin in Ischaemic Heart Disease (LIPID) (The Long-Term Intervention with Pravastatin in Ischaemic Disease (LIPID) Study Group 1998) Study Group also demonstrated a reduced mortality from CHD and overall mortality. This study involved 9,014 male patients aged 31-75 years of age with a past medical history of myocardial infarction or hospitalisation for unstable angina. Patients with a broader range of starting cholesterol levels 4.0 – 7.0mmol/l were recruited. A double-blind randomised control trial was carried out comparing the effects of Pravastatin 40mg once daily with placebo. Groups were again equally matched for smokers, hypertensives, etc, with 4,512 patients randomised to be treated with Pravastatin and 4,502 to the placebo. Results from the study revealed that mortality from CHD causes was 24% lower ($p<0.001$) in the Pravastatin group. This was attributed to a reduction in total cholesterol that was 18% greater than in the placebo group ($p<0.001$).

As new evidence emerges from clinical trials, the target cholesterol level changes and is widely debated. In 1998, the Joint British Guidelines (British Cardiac Society 1998) recommended a target cholesterol level of $\leq 5.2\text{mmol/l}$. This has subsequently been changed and even more aggressive target levels are desired. Recommendations from the Heart Protection Study (Heart

Protection Study Collaborative Group, 2002) reported patients with known CHD should have a target cholesterol level of $\leq 3.5\text{mmol/l}$ and medical management with Simvastatin 40mg OD should be sufficient to achieve this goal.

Undoubtedly as with the other coronary risk factors, patients should be encouraged to make appropriate lifestyle changes. There is evidence to support that in addition to the recognised benefits of lifestyle changes, good dietary habits, smoking cessation and increased exercise may contribute to reducing serum cholesterol levels (Gotto 1986).

2.5.5 Obesity

Obesity in adults is defined as a body mass index (BMI) >30 . The BMI is specifically called the Quetelet BMI, named after its creator Lambert Quetelet in 1869 (Sucharda 1989). Quetelet observed that in adults of normal build, weight was proportional to height squared. A hundred years later Keys et al made a similar finding and named the relationship BMI, see appendix III. In order to maintain a healthy weight (BMI 18.5-25) energy intake should be equivalent to energy expenditure. It is perhaps obvious that excessive sways in either direction will lead to individuals becoming underweight or obese.

A number of factors are considered to contribute to obesity, hormones, genetics and metabolic rate. However, it cannot be overlooked that a number of socio-economic forces also exist (Stunkard & Sorensen 1993). As a nation our current economic growth continues to rise. Modernisation has led to individuals undertaking less physical jobs, increased machinery and computerisation. Globalisation of food markets, introducing a wide range of convenience products, which are foods high in saturated fats and sugars. These factors are likely to have contributed to the incidence of obesity. In addition to this, a higher percentage of households are car owners (63-85%) (Office for National Statistics 2003) and as a result may undertake less physical activity, if any.

There are approximately 300 million obese people worldwide with an emerging epidemic of obesity in the UK (World Health Organisation 2006). A further one billion are thought to be overweight (BMI 25-30). The UK has the fastest growing rate of obesity in the developed world. Over the last ten years there has been an eight percent (14-22%) increase in the obese adult UK population. It is also of concern that one in four children in the UK are overweight or obese with a resultant growing incidence of type II diabetes emerging in adolescents (Diabetes UK & All-party Parliamentary Group for Diabetes and supported by the Hansard Society 2005).

Obese individuals have a two-fold increase of developing CHD (HEA 1990) and it is well recognised that dietary modification has a key role to play in not only obesity but in altering other CHD risk factors.

2.5.6 Inactivity

Industrialisation, urbanisation and mechanised transport have, as previously mentioned, significantly reduced the amount of physical activity we undertake today. Growing evidence is emerging demonstrating that regular exercise such as walking, swimming, cycling and dancing are of benefit in reducing the risk of coronary events in both primary and secondary prevention of CHD (Williams *et al* 1987). Despite this knowledge currently more than 60% of the worldwide population is not sufficiently active (World Health Organisation 2006) and this may be reflected in the growing incidence of obesity in the UK (section 2.4.5).

Regular physical exercise has proven to lower coronary risk factor profiles (Taylor *et al* 2002), however debate remains around whether or not it alters the presence or extent of atherosclerosis. There is evidence to suggest that reductions in fibrinogen and blood viscosity are observed in those who undertake regular exercise (Connelly *et al* 1992; Elwood *et al* 1993). Moreover, those who regularly undertake moderate to vigorous exercise are shown to lower BMI and insulin resistance (Taylor *et al* 2002), lower blood pressure and increase HDL cholesterol (Despres *et al*

1995). Individuals who have previously been physically active are not at less risk, as the benefits of physical activity cannot be saved and it is reported that individuals who do not undertake regular exercise have a two-fold increase in developing CHD (Morris *et al* 1990).

A Cochrane review of both men and women of all ages with known CHD demonstrated that exercise only cardiac rehabilitation reduced all cause mortality by 27%, cardiac death by 31% and a combined endpoint of mortality, non fatal MI and revascularisation by 19% (Cochrane 4, 2004). It is recommended in primary and secondary prevention of CHD that people should undertake regular exercise in order to benefit from the cardio-protective effects. How much exercise and in what form is unclear. Recommendations from the SIGN guidelines would suggest 30mins of moderate to vigorous exercise on most days may be beneficial (Scottish Intercollegiate Guidelines Network (SIGN) 2001). Other guidelines (British Cardiac Society, British Hypertension Society, Diabetes, HEART, Primary Care Cardiovascular Society, & Stroke Association. 2005) advocate the benefits of regular exercise, but do not state the quantity of exercise that should be undertaken.

2.5.7 Alcohol

Perhaps in contrast to other coronary risk factors, alcohol is reported to have an inverse association with CHD (Marmot 2001a) at low to moderate levels of consumption. Studies conducted have demonstrated that at such levels there may indeed be beneficial effects on the heart, lowering CHD risk. This is thought in part to be due to changes in platelet aggregation (Renaud *et al* 1992) and an increase in HDL cholesterol levels. But what is light to moderate drinking? Reviewing the literature there does not appear to be a clear definition of drinking levels. Even published guidelines are not consistent when defining recommended levels. SIGN (Scottish Intercollegiate Guidelines Network (SIGN) 2003) guidelines suggest that one “unit” of alcohol is approximate to 8g of ethanol. No definition of light or moderate drinking is given however it is specified that in excess of 5 units of alcohol a day for men and over 3 units of alcohol a day for women is hazardous.

It cannot be ignored that drinking excessive amounts and “binge” drinking are reported to increase coronary risk and can lead to sudden death (Corrao *et al* 2000). In addition, the effects of excessive or heavy drinking may contribute to increased mortality and morbidity from liver disease, hypertension and cancer.

2.5.8 Extent to which risk factors and intervention impact on CHD mortality

Determining the extent to which risk factor changes and medical and surgical interventions reduced Scottish CHD mortality was examined by Capewell *et al* (Capewell *et al* 1999). Using a validated mortality model (Critchley & Capewell 2002) developed by Capewell *et al*, data were collected over three decades from 1974 to 1994. A model combining effectiveness data from meta-analysis of treatment uptake in specific patient categories in Scotland was employed. Data from large epidemiological surveys, for example MONICA (Tunstall-Pedoe *et al* 1994), national health service sources and local audit were used to estimate how the above factors influenced CHD mortality. Where possible the absolute mortality benefit of specific treatments was determined. Patient categories examining medical interventions included; 1) initial treatment for acute myocardial infarction, eg, thrombolytic therapy; 2) secondary prevention following myocardial infarction, eg, treatment with Aspirin; 3) Treatment of angina in hospital, eg heparin ; 4) Angina in Primary care, eg, patients given Aspirin; 5) Treatment of hypertension, eg, antihypertensive therapy. Surgical interventions being examined included Primary Coronary Intervention (PCI), for example, angioplasty, and cardiac surgery, such as coronary artery bypass graft (CABG). Consideration was made for potential overlaps in the above groups and this was addressed using analysis of MONICA data (Tunstall-Pedoe *et al* 1994).

Trends in coronary risk factor changes were also examined, these included smoking, cholesterol, deprivation and blood pressure. Using mean values of these a regression analysis was undertaken.

An estimated benefit from the cumulative effects of treatments has been reported and this was factored into the analysis.

Following analysis of the data in 1994, the number of deaths from CHD within Scotland was actually 6,205 fewer than expected. Concurring with other similar work, Capewell *et al* attributed 60% of this CHD mortality reduction to changes in risk factors, with approximately a third related to smoking cessation.

2.6 Management of patients with CHD

Prior to 1998 individual British societies representing healthcare professionals worked independently, publishing separate guidelines specific to their field, but much of their goals were the same. For example, the British Hyperlipidaemia Association compiled and published guidelines on the management of hyperlipidaemia (Bettcridge *et al* 1993). In an attempt to achieve a common approach it was felt necessary to include all cardiovascular risk factors, rather than focusing on single risk factors and treating them in isolation (British Cardiac Society 1998). In order to achieve this hospital and community based clinical settings were encouraged to work together and integrate care developing new strategies for prevention and delivery of CHD care.

2.6.1 Joint British Guidelines

As a result of observing the work of European colleagues who published joint guidelines in 1994 (Wood *et al* 1998), the first Joint British Guidelines (British Cardiac Society *et al* 1998) were published in 1998. These joint guidelines were compiled by the British Cardiac Society, British Hyperlipidaemia Association, British Hypertension Society and endorsed by the British Diabetic Association. The purpose of the guidelines was to achieve a common consensus on the

management of patients with CHD. The guidelines provided an overview of the best current treatment based on the strength of results from large clinical and laboratory trials. Treatment targets for coronary risk factors were recommended as detailed below in table one.

Table 1 Treatment targets for modifiable risk factors

Risk factor	Target
Systolic blood pressure (SBP) mmHg	≤ 140
Diastolic blood pressure (DBP) mmHg	≤ 85
Total cholesterol mmol/l	≤ 5.2
BMI	≤ 25
Smoking	Total cessation

In addition to the above, recommendations for treatment with prophylactic medication were given, again based on the best evidence available from large clinical and laboratory trials at this time. These are discussed in more detail in section 2.7.

Incorporated into the guidelines was information regarding the use of risk prediction charts (Anderson *et al* 1991; Wood *et al* 1998), which allow clinicians to evaluate a patients relative risk of developing CHD. A number of risk prediction tools exist and have emerged as a result of large epidemiological studies, for example, information gathered over the last sixty years from the Framingham Study (Woodbury, *et al* 1979).

It is important to recognise that these charts were designed with the intention of use in primary prevention of CHD and must be used with caution in secondary prevention. Many of the recommendations for treatment in primary prevention, set out in the guidelines, are equally relevant in the secondary prevention management of patients with CHD. However, treatment targets for those with known CHD are set at a lower level.

2.6.2 Scottish Intercollegiate Guidelines Network (SIGN)

The Scottish Intercollegiate Guidelines Network (SIGN) was established in 1993, and has published a wide variety of guidelines developed by multidisciplinary groups across Scotland. Guidelines produced are as a result of systematic review and critical appraisal of current literature available. The recommendations set out in the guidelines are graded according to the strength of the evidence available and allows practitioners the opportunity to prioritise depending on local need. The purpose of producing such guidelines is to improve the quality of care and endeavour to standardise practice across Scotland.

The introduction of SIGN publications not only reassures practitioners that they are prioritizing key areas of importance, but also they are working to evidence based guidelines. Guidelines are distributed to general practices as they become available, however it is difficult to know how widely used these guidelines are, and in what context. Specific guidelines for the use in CHD (Scottish Intercollegiate Guidelines Network (SIGN) 2001; Scottish Intercollegiate Guidelines Network (SIGN) 2002) are available and provide a clear and comprehensive approach to managing patients with CHD.

2.6.3 National Service Framework (NSF)

Although not specific to Scotland, the first National Service Framework (Department of Health, 2000) published in 2000 set out twelve standards for prevention and treatment of CHD, each

supported by evidence from clinical trials including the role of primary care in secondary prevention. Standards one to four highlight the need for implementing policies that will monitor, treat and reduce CHD both in primary and secondary prevention, with emphasis on managing CHD in Primary care. This like SIGN proposed to improve the quality of care patients with CHD were receiving and also minimise the variation in both practice and outcome across England. Despite this publication being specific to England and CHD priorities, much of this is easily transferable to the Scottish population.

Patients admitted to hospital with a coronary heart disease (CHD) event should be invited to participate in a multidisciplinary programme of secondary prevention and cardiac rehabilitation, as recommended in Standard 12 of the *National Service Framework for Coronary Heart Disease* (NSF) (Department of Health, 2000). In addition, a large proportion of CHD patients who are managed in general practice and/or on a hospital outpatient basis and who may not have had the opportunity to attend formal cardiac rehabilitation programmes would benefit from appropriate secondary prevention. Cardiac rehabilitation programmes vary across the UK in terms of the patient groups who are eligible to join. Many limit access to post-myocardial infarction patients and post-coronary artery bypass patients only (Bethell *et al*, 2001; Thompson *et al*, 1997).

2.7 Overview of current practice

As previously discussed, a great deal of research in CHD management has been undertaken demonstrating the evidence base for best practice. Guidelines are widely accessible yet surveys continue to report sub optimal management in patients with CHD. In this thesis two key papers are used for reference and comparison. Both papers report on findings from retrospective casenote review and discuss risk factor assessment and management, and implementation of prophylactic medication.

As a result of changing national health priorities and new general practitioner (GP) contract (Department of Health 2003) there are now established criteria practices should work towards. In Glasgow a new chronic disease management (CDM) programme has been established, clearly identifying CHD as a priority area. Practices are being encouraged to implement structured comprehensive secondary prevention measures and regular external audit is being undertaken to assess whether practices are achieving targets set out in their contracts.

2.7.1 Surveys of secondary prevention management

Action on Secondary Prevention through Intervention to Reduce Events (ASPIRE) (Aspire Steering Group 1996) investigators undertook a retrospective and prospective cross sectional survey of patients medical records and patient interviews to measure how effectively CHD risk factors were being assessed and managed. The study looked at 2,583 patients aged 70 years and under using a stratified random sample of 12 specialist cardiac centres and 12 district general hospitals in the UK. Patients were grouped by gender and one of the following four main categories: Coronary Artery Bypass Graft; Percutaneous Coronary Angioplasty; admission with Myocardial Infarction and admission with Myocardial ischaemia without evidence of infarct. Review of medical casenotes involved documentation of risk factors and management prior to the CHD event and approximately six months after the CHD event. Medical note review was restricted to the hospital records, which may not give a true representation of documentation, however, results obtained from the interviews after the event summate this. Interviews and assessments were carried out at the General Practices and in the main study 83% attended. Findings revealed that documentation and management of risk factors was less than optimal.

In patients with known CHD, ASPIRE documented that 18-20% of patients surveyed were current smokers at the time of interview. It also noted that smoking was the most regularly documented

risk factor but very little was documented with regard to action being taken, for example, advice given to patients regarding smoking cessation. Blood pressure was also well documented,

Brady *et al* (Brady *et al* 2001) undertook the largest secondary prevention CHD survey of its time within the UK. A total of 24, 431 patients with a diagnosis of coronary heart disease had their casenotes reviewed. The patients were identified from computerised patient records, from a total of 548 general practitioners. Other practices were identified, but were excluded as they had previously had CHD audit undertaken, which could bias results.

Approximately a quarter of patients with CHD continued to smoke, this figure was slightly lower in ASPIRE, with approximately a fifth of patients documented as current smokers.

In both ASPIRE and Bradys work the amount of exercise undertaken by individuals was not documented.

The British Hyperlipidaemia Associations (BHA) guidelines (Betteridge *et al* 1993) first priority for treatment is patients with existing CHD, with a total cholesterol $\geq 5.2\text{mmol/l}$. In 'Aspire 72% of men and 83% of women had a total cholesterol $\geq 5.2\text{mol/l}$. It is important to recognise that the work undertaken by Brady *et al* was five years later and it was disappointing that no significant improvements were observed.

In addition to the above research EUROASPIRE (Wood *et al* 1997) undertook a comparative survey observing similar results to both ASPIRE and Brady. This work was subsequently repeated and unfortunately there did not appear to be any significant improvements in either risk factor stratification and management or implementation of prophylactic medication. This again reinforced the need to answer the research questions proposed in this thesis.

2.8 Prophylactic medication

The Joint British Guidelines (British Cardiac Society 1998) recommend that in addition to identifying and addressing known coronary risk factors, treatment for patients with IHD should also involve the implementation of evidence based prophylactic medication. Ideally patients should be prescribed all of the recommended therapies, namely antiplatelet therapy, beta blocker, statin and more recently angiotensin converting enzyme inhibitor (ACE I). However, in practice this is not always realistic due to contraindications and intolerances.

2.8.1 Antiplatelet therapy

Antiplatelet drugs are widely used in CHD and have been shown to reduce the incidence of MI (Antiplatelet Trialists' Collaboration 1994). The action of antiplatelet drugs is to reduce the aggregation of platelets in the blood, which may otherwise lead to thromboembolism and subsequent MI. Research undertaken by the Antiplatelet Trialists' Collaboration demonstrated significant benefit for not only those patients deemed at high risk, for example, unstable angina and suspected MI, but also, patients at high risk in other categories, such as peripheral vascular disease. Reductions in vascular events for the four main categories being examined; previous MI, suspected or definite acute MI, previous cerebrovascular CVD and other vascular disease, were each highly significant ($2P < 0.00001$) accounting for approximately one quarter. When examining patients at lower risk in the primary prevention groups, this also showed significant reductions in both non fatal MI and other vascular events ($2P < 0.0005$ and $2P = 0.09$ respectively).

Aspirin (Acetylsalicylic acid)

The use of aspirin, as an antiplatelet in secondary prevention of CHD is well recognized. For example, the Second International Study of Infarct Survival (ISIS-2) (ISIS-2 (Second International Study of Infarct Survival) Collaborative Group 1998) trial demonstrated a 23%

reduction in vascular mortality when comparing aspirin with placebo. However there is evidence to suggest that almost a quarter of patients are not prescribed this (Aspire Steering Group 1996; Brady *et al* 2001). Unless specific contra-indications or intolerances exist, aspirin 75mg daily is recommended for all patients with CHD (British Cardiac Society, British Hypertension Society, Diabetes, HEART, Primary Care Cardiovascular Society, & Stroke Association. 2005; Scottish Intercollegiate Guidelines Network (SIGN) 2001). The rationale behind giving a lower dose of aspirin being there are fewer documented side effects and research has shown this to be an effective dose (Antiplatelet Trialists' Collaboration 1994).

One explanation for the low prescribing of aspirin may be due to patients buying the drug 'over the counter' (OTC). Often patients are advised to start taking aspirin, however OTC aspirin is significantly cheaper than purchasing it on prescription, hence a large percentage may do this. Examining the literature, there was little published in this area; however, two UK surveys supported the author's thoughts. In a London survey examining post MI patients as many as 22% of patients on aspirin bought this over the counter (Hopper & Pierce 1998). Moreover, not surprisingly, those purchasing their aspirin OTC were patients who were still paying for their prescriptions. In another survey examining this area, 26% of patients using aspirin purchased this OTC (Bedson *et al* 2001). These figures could account for why research has previously found as few as 75% of CHD are prescribed aspirin. Examining the literature it is not clear whether or not general practice prescription records take into account only those patients paying for their prescriptions or if OTC aspirin is documented. This highlights an area for the author to focus on.

Adenosine Diphosphate (ADP) receptor antagonists

More recently Clopidogrel, an ADP receptor antagonist has emerged on the market as an alternative or additive to aspirin. This is a more potent antiplatelet agent, although significantly more expensive. In a trial of Clopidogrel versus aspirin in patients at risk of ischaemic events (CAPRIE) (CAPRIE Steering Committee 1996) Clopidogrel was shown to provide an additional 8.7% relative risk reduction, over and above the previously documented 25% risk reduction

shown with aspirin. The study concluded that Clopidogrel was expected to prevent approximately 24 major clinical events versus 19 with aspirin, for each one thousand patients treated for a year. However, at present Clopidogrel is only recommended in clinical practice for those patients who have either contraindications or previous intolerance to aspirin or deemed to be at higher risk of coronary events, for ACS, post PCI (Mehta, Yusuf, & Clopidogrel in Unstable angina to prevent Recurrent Events (CURE) Study Investigators. 2000).

2.8.2 Beta adrenergic blocking agents (β blockers)

Beta blockers work by decreasing the myocardial oxygen demand. This is done in a number of ways: reduction of the resting heart rate, reduction of the heart rate response during exercise, lowering blood pressure and lowering the force of ventricular contraction (The BHAT research group 1982). Similar to antiplatelet agents, the use of beta blockers in patients with IHD is well established (British Cardiac Society, British Hypertension Society, Diabetes, HEART, Primary Care Cardiovascular Society, & Stroke Association. 2005;Scottish Intercollegiate Guidelines Network (SIGN) 2002;The BHAT research group 1982). Beta blockers play an important role in not only the management of stable angina but also acute coronary syndrome and MI (British Cardiac Society, British Hypertension Society, Diabetes, HEART, Primary Care Cardiovascular Society, & Stroke Association. 2005;Roe, Parsons, Pollack, Jr., Canto, Barron, Every, Rogers, Peterson, & National Registry of Myocardial Infarction Investigators. 2005;The BHAT research group 1982). The choice of beta blocker varies between physicians, however some are known to be more cardio-selective than others, for example metoprolol and atenolol.

The majority of evidence supporting beta blocker usage was undertaken in patients post MI. Several studies undertaken in the 1980's clearly demonstrated significant mortality reduction with beta blockers. A landmark study in relation to beta blocker therapy was the first International Study of Infarct Survival (ISIS-1), which was undertaken between 1981-1985. A total of 16 027 patients entering 245 coronary care units (CCU) with suspected acute MI were randomised either to a control group or to a group receiving atenolol. This study demonstrated mortality reduction

within the first seven days post infarct from 4.3% to 3.7% in the treatment group. Similarly, a 13% reduction in sudden death was observed in post MI patients when propranolol was compared with placebo in the Beta Blocker heart attack trial (The BHAT research group 1982). Furthermore, meta analysis of clinical trials has demonstrated that treatment with beta blockers in patients with CHD can lead to a 59% reduction in frequency of silent ischaemia .

As with Aspirin, despite this knowledge the percentage of patients being commenced beta blockers following an MI still remains low. It has been reported that as few as % patients post MI are commenced on a beta blocker. A number of documented side effects and contraindications exist for this group of drugs and there may be reluctance from physicians to commence beta blockers in view of their potential side effects. Also, a lack of information exists at present regarding those patients who have discontinued therapy as a result of undesirable side effects.

2.8.3 Statins

The evidence base behind the use of statin therapy has been discussed previously in this chapter, section 2.3.4.

2.8.4 Angiotensin Converting Enzyme Inhibitors

Angiotensin Converting Enzyme Inhibitors (ACE I) inhibit the conversion of inactive angiotensin I to the powerful vasoconstrictor angiotensin II (Swanton 1989) and have historically been used in the management of chronic heart failure (CHF) and hypertension. More recently epidemiological and experimental data suggest that activation of the renin-angiotensin-aldosterone system plays an important role in increasing the risk of cardiovascular events and that the inhibition of angiotensin-converting enzyme would prevent events related to ischaemia and atherosclerosis (Yusuf *et al* 2000).

Due to its potential therapeutic implications The Heart Outcomes Prevention Evaluation study (HOPE) (Arnold *et al* 2003b), a landmark study, concluded early due to the clear evidence of Ramipril's value. . The purpose of the HOPE study was to examine the benefits of using Ramipril, an established Ace Inhibitor and Vitamin E in patients with no evidence of left ventricular systolic dysfunction or heart failure in a group of patients at high risk of cardiovascular events. Aside from reducing cardiovascular events it was reported that Ramipril had the potential to reduce stroke, by lowering blood pressure, and could also avoid the complications of diabetes.

The HOPE study, a double blind, two-by-two factorial, randomised study recruited a total of 9297 patients (aged 55 years or over) with evidence of vascular disease or diabetes plus one other cardiovascular risk factor. The primary outcomes for the study included (1) composite outcome of myocardial infarction (MI), (2) stroke or (3) death from cardiovascular causes. Secondary outcomes examined death from any cause, revascularisation, hospitalisation for unstable angina or heart failure and any complications associated with diabetes. Due to the large numbers used in the trial it was not thought feasible to undertake echocardiography on all the patients to establish ejection fractions, however, patients were not known to have a low ejection fraction (<0.40), (normal range >0.40) or heart failure.

Patients were assigned to Ramipril 10mg (n=4645) and placebo (n=4652). A sub study comparing low dose Ramipril 2.5mg with Ramipril 10mg was undertaken in the remaining 244 patients. Follow up was six monthly.

Results reported a clear 20% reduction in the relative risk of primary outcomes. Following further analysis patients in the placebo group had a 17.7%(824) incidence of death from cardiovascular cause compared with 14.1%(653) in the Ramipril group, relative risk, 0.78; $p<0.001$. There were also significant reductions in the Ramipril group in contrast to the Placebo group, (460 v's 567 ($p<0.001$) for patients with documented myocardial infarction and (157 v's 226 $p<0.001$) for documented stroke.

In conclusion, the findings of the HOPE investigators demonstrated that Ramipril is beneficial in a broad spectrum of patients with no known heart failure or left systolic dysfunction but who are at higher risk of cardiovascular events. The implications this has on physicians and practitioners is colossal, not only will it be recommended that Ramipril be incorporated into this group of patients but will in time undoubtedly become standard practice, even perhaps on a par with Aspirin usage.

2.9 Implementation of prophylactic medications

Following review of the literature it does appear that prescribing of aspirin, beta blockers and statins is sub optimal (Aspire Steering Group 1996;Brady *et al* 2001;Wood *et al* 1997). The current literature does not however give a clear indication of why uptake of these medications is poor. Computerised GP records are becoming more and more sophisticated and this may be one way to input more information around prescribing. Entering not only drugs prescribed but also drugs contraindicated or not tolerated may give a clearer picture. Owing to time constraints this is not an area the author will focus on in this research but certainly gives scope for further work.

2.10 Quality of Life (QOL)

Quality of life (QOL) assessment is a central element of clinical trials and associated forms of evaluative research. It is now an established end point used in clinical trials, however choosing the correct QOL measure must be carefully considered (Juniper 1998). The term QOL is often used vaguely and without clear definition (Beattie *et al* 1997).

In its broadest interpretation quality of life is a concept that should encompass all factors that might impact on a persons life and well being. It includes factors such as self-esteem, achieving

lives goals and a range of social, emotional and physical components. Evaluating observed changes in QOL as a result of a new healthcare intervention or treatment is mostly concerned with the impact on illness severity and general concepts of health status (Billingham & Jones 1999). This approach therefore can be variable depending on the definition of health being used, as well as the individuals interpretation of their status of well being. This is perhaps not surprising given many of the variables used in measuring QOL are subjective.

The WHO define health as *"a state of complete physical, mental and social well being and not merely the absence of disease"*. This definition has been used to develop many health related QOL scales and forms the basis of the short form 36 (SF-36) instrument used in the research for this thesis.

Two approaches to measuring QOL exist; they are generic or disease specific. Generic measures such as the Short Form 36 (SF-36) (Ware & Sherbourne 1992), the Sickness Impact Profile (SIP) (Bergner *et al* 1976), EuroQol (EuroQol Group 1990) and the Nottingham Health Profile (NHP) are designed to focus on general health and quality of life. One of the main advantages of generic measures is that they can be applied to a varied population in a number of disease areas and in the absence of disease. There are however disadvantages of generic measures. In terms of general health, generic measures may not always be as responsive to specific change, failing to fully represent the importance of changes made (Beattie *et al* 1997). For example, patients with a specific disease may have a small improvement in physical function. This may be very relevant to how this impacts on their general well being, however may be too subtle to measure.

Deciding which of the generic measures to use may be determined by a number of factors, scientific evidence, research questions, the population being studied and the nature of the study (Guyatt *et al* 1993; (Essink-Bot *et al* 1997).

Perhaps one of the most widely recognised generic measures of QOL is the SF-36. The SF-36, which was adapted from the Medical Outcomes Study permits scoring of a set of eight scales displayed as a profile of health status concepts. These include: 1) limitations in physical activities because of health problems; 2) limitations in social activities because of physical or emotional problems; 3) limitations in usual role activities because of physical health problems; 4) bodily pain; 5) general mental health (psychological distress and well-being); 6) limitations in usual role activities because of emotional problems; 7) vitality (energy and fatigue); and 8) general health perceptions. The SF36 has been designed for self-administration, telephone administration or administration during personal interview. For the purpose of the research for this thesis the SF36 will be used during phase II, forming part of an interview schedule (Ware & Sherbourne 1992).

In a review of QOL measures used in patients with CHD (Dempster & Donnelly 2000), the SF-36 was felt to have good psychometric properties. Similarly, a comparative study examining four generic health outcome measures (Essink-Bot *et al* 1997) identified the SF-36 as having the best ability to discriminate between groups, with high levels of internal consistency. It is deemed to be a reliable and suitable measure of health in a normal population (Jenkinson *et al* 1993) and for those with minor conditions.

Conversely, disease specific measures are designed with the intention of formulating questions around a specific disease area and its related health problems. Examples of disease specific measures within CHD include, the Angina Pectoris Quality of Life Questionnaire (Marquis *et al* 1995), the Minnesota Living with Heart Failure Questionnaire (Rector *et al* 1992) and the Cardiovascular Limitations Profile (CLASP) (Devlen & Maguire 1989). Disease specific measures are reportedly more sensitive to subtle changes in the disease area being investigated (Beattie *et al* 1997). However, as with generic measures, disease specific measures can be equally vague. Patients own individual experience can vary and this may influence how questions are answered. This variability in answering specific questions may not allow results to be generalised across the population being studied (Dempster & Donnelly 2000).

The CLASP measure is widely used within CHD, and can be used across a spectrum of cardiac areas (Department of Health, 2000; Lewin *et al* 2002; Smith, *et al* 2002). The CLASP comprises of 37 items, incorporating nine physical and functional dimensions. Included in the functional dimensions are mobility, social life and leisure activities. The physical subscales include angina symptoms, ankle swelling and shortness of breath. Scores are given to each domain and a CLASP score is generated. An examination of the reliability, validity and sensitivity of CLASP (Lewin *et al* 2002) found positive correlations in the majority of parameters studied. Some of the strengths highlighted in favour of CLASP included an ability to measure symptoms specific to CHD, the measure appeared to be sensitive to changes observed post intervention, and despite its length it was easy to complete. However, only patients with chronic angina were examined, and the majority of patients were, and had been stable for a number of years. Data were collected at baseline and 10 weeks, which is also a possible limitation in this cohort of patients. In 2000 the National Service Framework (Department of Health, 2000) recommended the use of CLASP as a suitable and reliable outcome measure in patients with CHD.

In the case of CHD, Dempster and Donnelly (Dempster & Donnelly 2000), concluded the disease specific measures were found to be too narrowly focused on each CHD area, for example MI, heart failure, and may not be transferable across different CHD groups. The review also considered that there is currently no 'gold standard' available to compare QOL measures used, as the criterion was so variable. This therefore reinforces that the decision regarding which QOL measure to use must be based on a number of factors related to the research questions and the nature of the study (Juniper 1998).

In summary, both generic and disease specific measures may be successfully used independently. However, in order to supplement and reinforce the generalisability and validity of results, a combination of the two may be chosen (Dempster & Donnelly 2000). Additionally, the design of

the questionnaire with regard to the type of questions being asked, length of questionnaire and complexity of questions are important factors.

2.11 Behavioural change

Helping patients to make change, irrespective of what the area of change may be, is often a common and difficult task during both nursing and medical consultations. For example, opportunistic screening may reveal a patient drinking excess amounts of alcohol. This may not be perceived as a problem by the patient, and they may not have considered the potential risks to their health. Discussing this as an area for attention can be both sensitive and difficult.

In view of the current health statistics in Glasgow pertaining to CHD (Section 2.2.4) much emphasis is now directed on health promotion and tackling issues such as smoking, obesity and exercise. Different models exist in describing components and concepts relating to behaviour change; Health Belief Model (Becker *et al* 1974), Social Cognitive Theory (Bandura 2004;Suminski & Petosa 2006), Theory of Reasoned Action (Donald & Cooper 2001), Theory of Planned Behaviour (Ajzen 1991;Droomers *et al* 2004) and Transtheoretical Model (Prochaska, *et al* 1992). The transtheoretical model is probably the one most commonly used in both training and the clinical setting today. The transtheoretical model and the 'cycle of change' described by Prochaska and DiClemente (Prochaska *et al* 1992) are perhaps better known as motivational interviewing, and are discussed in more detail below.

2.11.1 Motivational interviewing

Motivational interviewing as a technique emerged in 1983 as a result of the experience of Dr R Miller working in the treatment of problem drinkers (Janz & Becker 1984). This initial concept was later expanded and described in 1991 by Dr Miller and Dr S Rollnick. However, in 1995 owing to a number of interpretations around the concept of motivational interviewing, Miller and Rollnick described what they believed to be the definition of motivational interviewing;

"a directive, client counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence (Rollnick & Miller 1995)".

Motivational interviewing has four basic components, empathetic listening, encouraging patients to state their own reasons for change, roll with resistance, and support and self efficacy (Prochaska *et al* 1992). The main aim is to assess the patients readiness for change and then conceptualise this in terms of a 'stage' or 'cycle of change'. These individual stages of the 'cycle of change' are precontemplation, contemplation, preparation, action and maintenance. A later addition from Prochaska and DiClemente to the 'cycle of change' was 'relapse', suggesting that relapse is not defined as failure but as a normal part of the change process (Kushner *et al* 1998).

In essence, the 'cycle of change' model is an attitudinal model describing how people feel about making change rather than how they behave. The aim is not to dictate, but attempt to move patients through the process with the appropriate information and education in order to empower them to make their own choices. Success may be measured as forward movement from one stage to another, rather than ultimate cessation of the activity (Rollnick & Miller 1995).

2.12 Nurse-led Intervention

2.12.1 Introduction

The first reports of early day nursing go as far back as the early nineteenth century, with most of us familiar with the 'lady of the lamp', Florence Nightingale (Nightingale 1859). Nursing roles undertaken at this time have continued to develop, however prior to the 1950's evaluating these new models of nursing care was not routinely examined. It was not until the late 1950's, early 1960's that there appeared to be a greater focus on examining these roles in terms of clinical

effectiveness. Part of the impetus for this shift was to recognise the changing role of nurses and also to disseminate this information to other nurses in order to encourage practice development (Bigbee 2005).

2.12.2 Advanced nursing roles

A number of nurse specialist and advanced nursing posts exist in the United Kingdom, although as previously mentioned little attention has been given to evaluating these roles in terms of clinical effectiveness (Castledine 1993). With the expansion of nursing roles comes a variety of titles; Nurse Manager (NM); Specialist Nurse (SN); Clinical Nurse Manager (CNM); Clinical Nurse Specialist (CNS); Nurse Practitioner, Advanced Nurse Practitioner (ANP) and more recently Nurse Consultant (NC).

Newer nurse specialist (NS) roles exist in almost every area of nursing, for example, palliative care, stoma care, respiratory, and cardiology. Some evaluation of these roles has been undertaken but this is predominantly based on patient satisfaction surveys and clinical audit. Despite this lack of effectiveness data, nurse specialist posts continue to be developed in new areas of health care in response to reduction in junior doctor hours (Department of Health 1993) and recognition of unmet health care needs.

There is also a degree of confusion over the exact definition of the clinical nurse specialist and also the qualifications required to undertake such a role. In 1994 the UKCC described a NS as a *"practitioner who exercises higher levels of judgement and discretion in clinical care in order to function as a specialist nursing practitioner"* (UKCC 1994). Although this gives some guidance it is still fairly vague and over ten years on this role is open to a variety of interpretations. This similarly applies to the nurse consultant post, which will be discussed in the next section.

2.12.3 Nurse Consultants

In 1998, Tony Blair, the current Prime Minister, announced proposals to introduce Nurse Consultant (NC) roles within the NHS. This was in part proposed as a result of experienced staff leaving clinical posts to advance their career and increase their potential earnings (NHS Executive 1999). Details of these proposals were outlined in *"Making a Difference: Strengthening the nursing, midwifery and health visiting contribution to health and healthcare"* (NHS Executive 1999). As previously discussed, many nurses are working under advanced nursing titles, but what makes the NC different? It would appear that this is an ongoing debate (Bryant-Lukosius *et al* 2004). The UKCC differentiates the NC from other advanced practitioners stating it is the extent, level and complexity of their practice that makes them different. At present the remit of the NC posts is variable and evaluation of these posts limited. The specifications as to what postgraduate educational is required are unclear (McCreaddie 2006). However, there is a common feeling that a Masters degree, with emphasis on the research component (Woodward *et al* and Caring for Scotland 2001) is recommended. A difference in the nature of the NC role between Scotland and England has been observed (Manley 1997; Manley 2000) with Scottish nurse consultants performing a more defined "lead nurse" role than English counterparts. Reasons for this are unclear, but it possible that this is due to the driving forces behind these posts, at a government level.

2.12.4 Cardiac Nurse Specialist Roles

Within the cardiology setting there are a number of NC posts in practice, however the majority are in fact south of the border (McCreaddie 2006). Again, it is unclear why this exists, but may stem back to different political drivers. Fast track chest pain (Pottle 2005), Nurse led DC Cardioversion and Atrial Fibrillation Clinics (Tagney 2005) are a few examples of areas within cardiology where NC's have been established. *The CHD and Stroke: Strategy for Scotland, 2002* (Scottish Executive 2002) highlighted opportunities to extend the scope of nursing practice, supporting local CHD initiatives. Within Glasgow, the Managed Clinical Network (MCN) for

CHD were encouraged to develop consultant therapist and specialist nursing posts in accordance with service development (Scottish Executive 2002).

There are many examples of advanced nursing practice in the provision of cardiac care in both primary and secondary care, nurse led thrombolysis (Armstrong 2003), heart failure liaison nurses (Blue *et al* 2001), and nurse led chest pain clinics (Pottle 2005). Such advanced roles have now been widely established and accepted in the management of patients with coronary heart disease (Joss & Lindsay 2003). For patients awaiting coronary artery bypass graft surgery, McHugh *et al* (McHugh *et al* 2001) demonstrated that a specialist nurse-led programme can improve coronary risk factors, anxiety and depression levels, and general health and well being.

There is growing evidence of the effectiveness of nurse-led secondary prevention interventions for patients with CHD, with large randomised control trials also highlighting principles of good practice (Campbell *et al* 1998a; Jolly *et al* 1999). The following are examples of work in this area:

A randomised control trial was conducted in a Primary care setting in the North of Scotland to evaluate the effectiveness of nurse-led clinics at improving secondary prevention strategies for patients with CHD (Campbell *et al* 1998c; Campbell & Murchie 2004). Nineteen general practices were recruited and patients under 80 years, with a documented diagnosis of CHD were identified from computer databases and searches for repeat prescription of nitrate therapy. Patients (n=3,172) were identified and after screening for exclusion criteria (terminal illness, severe mental illness) and those not wishing to participate a total of 1,343 patients agreed to take part. Patients were stratified by age, sex and general practice and randomised to nurse-led intervention (n=673) or to a control group (n=670) (usual care from their GP and practice nurse). Every patient was encouraged to attend one visit within the first three months. Follow up ranged from two to six monthly. The clinics monitored symptoms, drug treatment, blood pressure, lipids and behavioural risk factor changes.

Data were collected prior to commencement of intervention, and at one year. Clinical outcome measures were gathered by review of medical notes. Data on Aspirin usage, diet, exercise and smoking were collected by means of self-administered postal questionnaires.

Significant changes in the intervention group were achieved from baseline to one year for Aspirin usage (taken or contraindicated by allergy or ulcer) 69.4% vs. 81%; Blood pressure ($<160/90\text{mmHg}$) 86.7% vs. 96.5%; Lipid management ($\leq 5.2\text{mmol/l}$) 12% vs. 41.1%; Low fat diet (DINE score <30) (Roe & Strong 1994) 49% vs. 56.5%; and Exercise (index of physical activity >4) 37.6% vs. 42.1%. The results from this study demonstrate that intervention improved all aspects of secondary prevention except smoking ($n=482$ smoking at baseline and $n=483$ smoking at one year).

A different model was approached in the Southampton heart integrated care project (SHIP) (Jolly *et al* 1999). This also involved a randomised control study examining the impact of nurse-led care, the model of care delivery was however different. The study assessed the impact of coordinated care programmes for patients with a new diagnosis of MI and angina discharged from hospital. The nurses involved in the study were specialist cardiac liaison nurses, their input was not in providing clinical care but in coordinating care at hospital discharge. The purpose of the intervention was to facilitate better communication between primary and secondary care and provide structures follow up for the nurses in General Practice. A total of 67 GP practices in Southampton and southwest Hampshire were randomised, to intervention ($n=33$) and to control groups ($n=34$). Outcome measures of BMI, blood pressure and total cholesterol were collected before hospital discharge, and at the completion of the study. Those patients recruited to intervention were given a programme to coordinate preventive care led by the nurse specialists with evidence-based guidance on clinical management attached to each discharge communication. Communication between the nurse specialists, practice nurses and GPs was encouraged to manage problems. The control group were given usual care from hospital and GP.

Both groups were followed up by self-administration questionnaires at one month, 4 months and one year. Anxiety and depression were assessed using HAD scales (Zigmond 1983) and the EuroQol (EuroQol group 1990) visual analogue scale were incorporated into the questionnaires. A total of 597 patients (422 with MI and 175 with Angina) were recruited to intervention (n=277) and to control (n=320), results were available on 502 at one year with 10% lost to follow up. Patients (at baseline) were similar in age, sex, smoking history, BMI, total cholesterol and blood pressure in both groups. Liaison nurses carried out a clinical assessment at one year. Data were analysed on an intention to treat basis but excluded deaths. There was no significant difference between the intervention and control groups in smoking (19% v 20%), lipid concentrations (5.8 v 5.93mmol/l), blood pressure (84 v 85mmHg), or fitness (distance walked in 6 minutes 443 v 433m). Body mass index was slightly lower in the intervention group (27.4 v 28.2; p=0.08).

These results were thought to be successful from a methodological and logistic perspective, intervention was implemented effectively and loss to follow up small. However, the intervention was ineffective in reducing risk, authors of the study indicated health promotion leaflets (issued to the patients in the intervention group) may be partly responsible for this lack of effect, namely the leaflets issued gave the wrong messages to the patients regarding recovery time. Another explanation for this lack of effect was 'the liaison nursing service could not influence local service provision within the framework of the programme'. Each GP practice appeared to work with their own standards of practice, which effectively limited the potential benefit the liaison nurses could achieve. This possibly is one of the limitations of the study; communication with the particular practices prior to commencement of the intervention and agreeing targets and standards may have achieved more favourable results.

These two studies produced very different results, one advocating the implementation of nurse-led clinics the other demonstrating little effect from nurse-led care. The main difference appears to be that of the degree of clinical input from the nurses (allowing for the statistically significant improvements in cardiac risk factors). Patients participating in the Campbell study were reviewed

by the nurses and were actively managed with regard to drug initiation and titration, goal setting for risk factor modification, etc, with good effect, whereas the specialist cardiac nurses in the SHIP study had little clinical input to care and had to rely on the patients GP or practice nurse implementing the particular discharge care plans.

Nurses have a key role to play in promoting secondary prevention. Different models of care exist and these at present predominate within secondary care. The way forward may be to shift the emphasis towards adopting integrated care pathways working across the primary and secondary care interface (Joss & Lindsay 2003). With the introduction of managed clinical networks (MCN), (Section 2.2.4) there is huge potential for nurses to be involved with the secondary prevention management of patients with CHD.

2.13 Conclusion

From the literature covered there is strong evidence to support the burden coronary heart disease (CHD) has on our society. A great deal of research has been published in the literature contributing to our understanding of the disease process and its contributing risk factors. This, and evidence from clinical pharmaceutical trials has been used to develop clinical guidelines for best practice. Despite this, the literature reviewed repeatedly demonstrates sub optimal CHD risk factor and medical management of patients. More effective measures of health promotion, care management directed to achieve risk factor targets and education are clearly reported in the literature.

Further, the evidence from the literature supports that nurse-led care is effective in managing patients with coronary heart disease. In this study I hope to illustrate that by integrating a Cardiac Nurse Specialist (CNS) between Primary and Secondary Care, to manage patients with CHD, could result in better implementation of recommended evidence based practice, reduce risk factors, improve quality of life and have the potential to reduce morbidity and mortality from CHD.

Research Questions:

- What level of coronary risk factor documentation occurs in medical casenotes for those patients with known CHD?
- How effectively are patients with CHD managed in relation to reaching recommended target levels for coronary risk factors?
- What percentage of patients with CHD are prescribed evidence based prophylactic medication?
- What is the general health of patients with CHD as determined by the presence or absence of coronary risk factors?

- What are the perceptions of patients with regard to their current general health?
- How motivated are patients with CHD in making appropriate lifestyle changes?
- How effective is a specialist cardiac nurse (in Primary Care) in improving and managing CHD in those patients motivated to make healthy lifestyle changes?

3.0 Literature Pertaining to Methods

3.1 Introduction

In this thesis a number of different research methods and tools were employed. The research was undertaken in two phases (see chapter four). For the purposes of this thesis a quantitative approach was used to evaluate the effectiveness of a cardiac nurse specialist (CNS) in the management of patients with coronary heart disease (CHD). Phase I consisted of a retrospective descriptive casenote review of the presence of cardiac risk factors. This preceded a prospective observational study, which examined both the perceived health status of patients with CHD, and, the presence of current coronary risk factors. The postal questionnaire also identified those indicating motivation to make healthy lifestyle changes. Phase II employed a randomised control trial of a new care model. This chapter explores the importance of planning research design and examines the data collection tools chosen.

3.2 Research Design

To answer the research questions careful consideration must be focused on identifying an appropriate research design. The question of research design has been described by Parahoo (Parahoo 1997a) in its simplest form as the *"how, when and why"* data should be gathered and analysed. Furthermore, in categorising research design Parahoo describes three main types of research, namely experimental research, survey research and case study. Grimes and Shultz (Grimes & Schulz 2002) on the other hand describe only experimental and observational research. Both contribute to the principles underpinning research design.

Experimental research aims to examine the relationship between the variables under study. This design is further divided into randomised and non-randomised research. Randomised control trials (RCT) will be discussed later in this chapter (Section 3.6). Observational research can be analytical, where a research question is broken down into layers in order that the researcher can obtain a better understanding of the subject, or descriptive. At a descriptive level there is no comparison group. The main purpose of the research is to explore the findings and describe what has been discussed about the area under study. One big advantage of descriptive studies is that having obtained results a hypothesis can be posed and examined by means of more stringent research, for example, a randomised control trial (Grimes & Schulz 2002). Other considerations in planning the research design with regard to data type are whether the data should be treated retrospectively, prospectively, quantitatively, qualitatively or by a mixed method. These data will be discussed further in section 3.7. The importance of a good research design following review of the literature is well established; the next step is to consider the ethical implications of the proposed research.

3.3 Ethical considerations

Early reports of medical ethics date back to 1926, with an association called *'l'Association Professionnelle Internationale des Médecins'* (World Medical Association 2004), which as a result of concerns over surgical practice, was responsible for suspending surgical procedures. This association was in fact the beginning of a movement to protect the well being of individuals under the care of physicians. In 1947, it was replaced by the 'World Medical Association' (WMA) and evolved quickly. At this time, owing to the casualties of World War II, there was grave concern surrounding a lack of medical ethics. The WMA united and compiled ethical guidelines in an attempt to improve practice standards (World Medical Association 2004). From 1947 to the late 1950's codes of practice were being developed and the WMA continued to monitor and report code violations. However, as a result of the atrocities which were observed

during the Nuremberg trials (Seidelman 1996), the WMA drafted the first 'Declaration of Helsinki' (World Medical Association 2004). The document outlines fundamental standards to be considered prior to undertaking a research project. The declaration clearly states *"It is the duty of the physician in medical research to protect the life, health, privacy, and dignity of the human subject"* (World Medical Association 2004). This should be key in undertaking research and remembered throughout the project period. It is also important to recognise that patients involved in research should be volunteers and adequately informed regarding the nature of the research. Informed consent is discussed in the following section.

Before any research project is undertaken, it is the responsibility of the researcher to obtain ethical approval, which is normally obtained from the appropriate Local Research Ethics Committee (LREC). Each health board should have access and information on relevant LREC's (HMSO 1998).

3.4 Subject recruitment and consent

In obtaining ethical approval for any study, the ethics committee needs to ensure that a number of important criteria pertaining to recruitment and consent are satisfied. First, the correct number of patients for the study should be calculated by means of undertaking a power calculation (Bland 1990). Statisticians Gore and Altman (Altman 1980; Gore 1981) stress the need for the correct choice of sample size for any study. Recognising not only the statistical implications on the study they highlight upon the ethical implications if sample size is not carefully considered prior to commencement of study. A study with an overlarge sample may be deemed unethical through unnecessary involvement of patients and increased costs incurred. By contrast a study with too small a sample size will be unable to detect any clinically important effects, therefore the research question may remain unanswered. Once the appropriate number of patients has been agreed and ethical approval sought the patients can be contacted.

Patients participating in the research process must be volunteers and should be fully informed and give their consent freely, in written form (Abbott & Sapsford 2002a). Detailed in the 'Declaration of Helsinki' (World Medical Association 2004) is the importance to clearly inform patients approached for any research of the aims, methods and proposed benefits of the study. It is equally important to highlight potential dangers which they could encounter. Patients should be allowed time, where applicable, to consider their decision. This may not always be ideal as occurs, for example, in the case of thrombolytic trials where the speed of drug delivery may determine outcome (Hillegeass & Brott 2005). In addition, all patients approached should be aware of their right to withdraw from the study at any time without it affecting their subsequent care (Cormack *et al* 1998). Finally, patients should never feel threatened or coerced into agreeing to participate in the research.

3.5 Randomisation

Randomisation quite simply refers to allocating either patients or variables randomly to a particular group. For example, pulling names from a hat to decide who plays in a team. When applied to research the most common use of randomisation is in a randomised control trial (RCT). This will be discussed further in the next section (Section 3.6). The process of randomisation in research plays a number of roles and different trial designs will require different procedures (Abbott & Sapsford 2002b). In undertaking randomisation it is suggested that allocating patients in blocks provide a better guarantee that treatment groups will be of equivalent size. In addition, stratifying the samples by important prognostic factors at baseline may have a cumulative effect of balancing allocation within strata, which may be of more potential benefit in smaller trials (Karlberg 2000). One of the main advantages of randomisation is that it helps the researcher to control possible extraneous variables, that is, it reduces the chances of allocation bias (Cormack *et al* 1998; Parahoo 1997a).

3.6 Randomised Control Trials

Phase II of the study employs a randomised control trial (RCT). The RCT is described by Grimes and Shultz (Grimes & Schulz 2002) and many others (Clancy 2002; Moher *et al* 1994; Parahoo 1997a) as the “gold standard” in research. A randomised control trial (RCT) is an experiment in which patients are randomly allocated to one or more group. One of the many strengths of the RCT is that it allows one not only to observe findings but also to compare results. In allocating a group to control the researcher is able to determine what would have happened to the patients if they had not had the treatment (Karlberg 2000). As discussed in section 3.5, the control and test groups should have similar baseline values as any bias here may skew the actual results of the effect of the treatment.

Clancy (Clancy 2002) is however sceptical of the RCT suggesting that they are expensive and artificial. By the latter is implied that treatment given to patients in these trials is superior to that given in the real world of health care, and cannot be replicated in normal practice.

3.7 Data collection methods

As mentioned in section 3.2, there are many ways to collect data. For this thesis a mixed method of data collection was used. The following subsections explore the different methods of data collection used in undertaking this thesis.

3.7.1 Reliability and Validity

If research is to be of value, then it must address the issues of reliability and validity (Cormack *et al* 1998). Reliability refers to the issue of whether or not a method of measurement works

consistently in producing similar results in similar situations (Abbott & Sapsford 2002b).for example, in this thesis blood pressure will be measured, two nurses taking the blood pressure within a short space of time should obtain the same or very similar result.

Parahoo (Parahoo 1997a) defines a method as valid when it measures what it sets out to measure. Pre testing and pilot studies give us the opportunity to examine whether or not we get the expected answers. There are a number of validity tests that can be applied. For the purposes of the questionnaires face validity (commonly referred to as content validity) will be used. In effect, face validity involves giving the questionnaire to anyone, not necessarily an expert on the subject, who can 'on the face of it' assess whether the questions reflect the phenomena being studied. Similarly, by administering the questionnaire to others this enables them to comment on the user friendliness. It also allows suggestions to be considered for possible changes and/or alterations to design prior to commencing the main study.

3.7.2 Retrospective and Prospective Data

In the design of this thesis both retrospective and prospective data were collected. In gathering retrospective data the researcher is able to understand what has happened in the past and in the particular area of interest. For example, a retrospective casenote analysis examining the documentation around breaking bad news (Barnett *et al* 2002) reported that although practitioners recorded that patients had been spoken to, little other information was documented. One of the main disadvantages of this design is the lack of control over the way in which data were previously collected (Parahoo 1997a). Data may be missing or illegible and documentation may be recorded out of context. In the example used above, staff may have indeed covered all the relevant areas pertaining to this event, however it cannot be assumed. This therefore can lead to misinterpretation of the facts. Conversely, in prospective data a greater control over data collection is achievable. The researcher is able to pre-determine the variables to be collected with

a greater assurance of having complete data. With prospective data the subject selection can also be tighter.

3.7.3 Quantitative and Qualitative Research

Data may be generated using a variety of methods and quantitative and qualitative research is often described in the literature. For the purpose of this study quantitative research has predominantly been chosen, but to illustrate why this method has been chosen, both methods are discussed below.

The main methods employed in quantitative research are *predetermined*, namely the research questions and design are fixed prior to commencing the study; *structured*, variables to be studied are decided in advance, minimising the work to the researcher and participant, and finally, *standardised*; each participant is asked the same questions in the same format (Parahoo 1997a). Unlike qualitative research, which is more open to change, quantitative research is ordered and predictable in its delivery. Quantitative research is typically conducted within the context of previous knowledge (Cormack *et al* 1998). In quantitative research the aim is to measure a particular phenomenon. Values or scores are attached to each variable being studied, which allows statistical analysis to be undertaken. Qualitative research, by contrast, is more holistic and open to the interpretation of the individual researcher. Qualitative results are more frequently described in terms of patterns and themes “observed” rather than “measured” as in a quantitative design.

Both methods of research are open to scrutiny and disadvantages to each are proposed. One of the main limitations of qualitative research is the subjective nature of the research, which is felt to be subject to researcher bias. In addition, it is argued that it lacks reproducibility and generalisability (Mays & Pope 1995). Undoubtedly there are disadvantages in quantitative research. It may be limited as a result of the inflexible structure, and according to its critics, the

quantitative approach yields useful but limited data and provides only a partial view of the phenomena being investigated (Parahoo 1997a).

The ultimate decision should be determined by the researcher, and again reinforces the need for careful consideration in research design. Both methods are capable of providing valid results, but, for the purposes of this thesis it was felt that a quantitative method would yield the best results. Owing to the design of the interview schedule employed in phase II there is little opportunity for qualitative data to be collected. This has been chosen specifically due to the time constraints on the appointments and volume of patients being studied. In phase I part B, the postal questionnaire (appendix VII) gives the opportunity for qualitative data to be gathered and this is presented in chapter 5.

3.8 Introduction to Data Collection Tools

Of equal importance in the research design is the correct choice of data collection tools. This phase in the research process offers a variety of possibilities. Each data collection tool has its limitations (Cormack *et al* 1998) and therefore it is important to choose the one which best meets the needs of answering the research question. The following subsections discuss the data collection tools chosen for this thesis.

3.8.1 Questionnaires

One of the most common methods of undertaking research involves the use of questionnaires (Walonick 2005). Structured self-reported data are usually collected in a quantitative study by this means. A questionnaire may be defined as a formal written document (Polit and Hunglar 1997) and is an umbrella term for different instruments (Cormack *et al* 1998). When

administered to be completed by the patients themselves, for example, postal questionnaires, this is referred to as a **questionnaire**. Alternatively, when the questions are asked face-to-face with the patients this may be referred to as an **interview schedule** (Abbott & Sapsford 2002a; Parahoo 1997a). A postal questionnaire will be employed in phase I part B of this thesis (appendix VII) and an interview schedule will be administered in phase II (appendix VIII).

Parahoo describes the questionnaire as a '*research method when it is designed and administered solely for the purpose of collecting data as part of a research study*' (Parahoo 1997a). In constructing the questionnaire, questions must be relevant, clearly presented to minimise misinterpretation or bias and must be easy to interpret and analyse. The questionnaire should contain specifically designed questions which will answer the research questions.

3.8.2 Postal questionnaires

Many of us have had experience of completing questionnaires and some may have experience of postal questionnaires. Postal questionnaires offer many advantages to the researcher and are a useful method of reaching a wide population (Cornack *et al* 1998). In addition they incur less time and cost and patients are able to answer in their own time and at their convenience. Another advantage with this method is the knowledge that there is no interviewer bias (Walonick 2005). Undoubtedly there are limitations to the postal questionnaire. Questionnaires may not be completed in their entirety and there is no assurance as to who has completed the questionnaire. It should also be remembered that literacy levels and language barriers exist and could have an impact on how questionnaires are completed and their resultant response rate.

Response rate is a major concern in administering postal questionnaires and low response rates may affect the reliability of the data, introducing bias (Edwards 2005). High response rates are reportedly more difficult to achieve with the literature suggesting higher response rates occurring as a result of a well-designed questionnaire (Walonick 2005).

3.8.3 Interview Schedules

Due to the time and cost involved in undertaking interviews a smaller sample of patients is normally investigated. In undertaking a face-to-face interview there is scope for the interviewer and interviewee to be more flexible. Although in the case of quantitative research the questions are delivered in the same format each time, there are possibilities for the respondents to add qualitative data in support of their answers. The interview schedule should be planned in such a way that the process is standardised fulfilling its role as a scientific instrument (Cormack *et al* 1998). The quality of the data collected during the course of the interview is very much dependent on the manner of the interviewer. The main advantage the interview schedule has over the postal questionnaire is its ability to reduce the very limitations postal questionnaires pose. For example, there is less chance of questions being omitted, and clarification of ambiguous questions can be addressed. Moreover, the researcher can be assured responses are not contaminated by outside influences, for example, questions answered by a partner or friend. In a survey undertaken by the government it was reported that up to 10 percent of the responses were completed by someone other than that intended. Finally, the interviewer is able to assist with minimising language and literacy barriers.

As with all areas of the research process, limitations to this method exist. In interviews, interviewers can read the body language and take it as cues to probe further, if appropriate (Cormack *et al* 1998). Critics will also argue that the interviewers may use voice inflections and body language to influence the way a question may be answered.

3.9 Construction of questions

The decision regarding question format is very much dependent on the type of data the researcher wishes to gather (Parahoo 1997a). In constructing the questions the aim is to collect valid and

reliable data, which can be easily administered and analysed. Question formats include, *open, closed and rating scales*. The merits of each are discussed below.

3.9.1 Open questions

Open questions are designed in such a way that they allow the subject to answer in their own words. They allow more flexibility in answering, but make analysis of these responses more difficult and time consuming (Cormack *et al* 1998). An example of an open question is:

What areas of nursing research do you feel are important?

Patients may give short or lengthy responses or may indeed be unwilling to answer at all. In the case of postal questionnaires this is undoubtedly a disadvantage as questionnaires may be returned incomplete, or indeed not returned. Open questions are ideally suited to qualitative research studies, and in particular their use in interviews.

3.9.2 Closed questions

In contrast, closed questions have the advantage of restricting the response alternatives. The purpose of using questions with such a high degree of structure is to ensure comparability of responses and to facilitate analysis (Parahoo 1997a).

The format of closed questions can be restricted to one of two options (*dichotomous*) for example:

Do you own a car: yes/no?

Nurse led care is effective: agree/disagree

Closed questions can however be constructed to allow more freedom of choice in responses (*alternative statements*) and can also allow respondents to give one or more answer, for example:

What factors influence where you work:

Staffing levels ()

Work pattern ()

Travel time ()

Wages ()

Another advantage of the closed question format is the speed in which the questionnaire can be completed, therefore minimising the risk of respondent fatigue (Cormack *et al* 1998). Closed questions do however have the disadvantage of being more difficult to construct and the major drawback is that the researcher may overlook important features when constructing question design. In addition, owing to the restricted options of responses the patients are obligated to choose the one that best suits them but may not truly represent their feelings

Both a postal questionnaire and interview schedule are employed in this thesis (see chapter 4) and are constructed with predominantly closed questions, and few open-ended questions. As discussed in section 3.7.2, this decision was made due to time constraints.

3.9.3 Rating scales

People's attitudes are said to be composed of affective, cognitive and behavioural components (Spooncer 1992). Measuring individuals' attitudes through observation is difficult therefore another method should be applied. Rating scales are considered to be a reliable and valid method of collecting information about patients attitudes and beliefs (Cormack *et al* 1998; Parahoo 1997a). A number of different rating scales exist but for the purposes of this thesis the Likert method (Likert 1932) and Semantic differential (Osgood 1957) have been chosen.

Likert scales

The Likert method will be used in phase I part B of this thesis (Section 4.13.1). Likert scales are widely recognised in all areas of research, for example, these scales are often used by holiday companies to evaluate customer satisfaction. The likert scale consists of pre defined statements pertaining to a particular issue or event (Cormack *et al* 1998). An opinion statement is made, for example:

- Nurses are adequately trained to deal with breaking bad news to relatives

The extent to which the respondent agrees or disagrees to this opinion statement is rated on the likert scale. The first point on the scale may read, “strongly disagree” with a decreasing range of negative responses, ending perhaps with “strongly disagree”. Likert scales are commonly 5 point scales however they have the advantage of being flexible and researchers can construct their own number of possible responses to best answer the research questions.

Semantic Differential Scales

Semantic differential (SD) scales will be used in phase II of this thesis (Section 4.18) to gather data pertaining to patients cardiac symptoms and management of the same. According to Bowles (BOWLES 1986) the semantic differential model ‘is a highly acceptable and frequently used measure of attitude and lends itself to statistical techniques for validation purposes’. The semantic differential scale is a tool used to rate a given concept on a series of bipolar adjectives. Patients are asked to plot a point on the seven point scale that goes from one extreme to another, for example, angina does not affect quality of life to angina dramatically impairs quality of life. The SD has the advantage of being flexible and easy to construct (Polit & Hunglar 1997). The SD scale and the visual analogue scale are very similar in appearance and both measure attitudes, however patients using the visual analogue scale have a continuous line to plot their response. This although easy to administer and analyse is not ideal for patients with visual impairment and the concept of plotting emotions and attitudes like this if not always understood (Parahoo 1997a).

3.10 Pre validated research tools

3.10.1 Introduction

The question of reliability and validity has been discussed (Section 3.7.1 & 3.8) and highlights the importance of choosing the right data collection tools to answer the research question. A number of 'pre validated' research tools exist. That is, questionnaires which have been constructed and tested for their reliability, validity and generalisability (Long & Johnson 2000). For the purposes of this thesis the short form 36 (SF36) (Ware & Sherbourne 1992) discussed below, was chosen as the most robust tool to examine quality of life.

3.10.2 Short form 36 (SF36)

As previously discussed in section 2.9, instruments designed to measure health related quality of life (QOL) can be divided into two categories, disease specific and generic. In order that the scores are of practicable benefit to clinicians they must produce valid data. In the case of the SF-36 (Ware & Sherbourne 1992), several studies have been undertaken examining the validity and reliability in both normal patient groups and across differing patient groups with regard to diagnosis and socio-demographic characteristics (Jenkinson *et al* 1993).

The Short Form 36 (SF36) permits scoring of a set of eight scales displayed as a profile of health status concepts: 1) limitations in physical activities because of health problems; 2) limitations in social activities because of physical or emotional problems; 3) limitations in usual role activities because of physical health problems; 4) bodily pain; 5) general mental health (psychological distress and well-being); 6) limitations in usual role activities because of emotional problems; 7) vitality (energy and fatigue); and 8) general health perceptions. The SF36 has been designed for self-administration, telephone administration or administration during personal interview. For the purpose of this study the SF36 will be used during phase II, forming part of an interview schedule (Ware & Sherbourne 1992).

In a review comparing generic measures in patients with IHD, it was concluded the SF-36 was most favoured (Dempster & Donnelly 2000). This was found to have good psychometric properties and appeared to have better construct validity in the field of IHD. In addition, higher internal consistency coefficients were found allowing clearer evidence of discriminative validity.

4.0 Materials and Methods

4.1 Introduction

This chapter details the measures and methods employed in the design, preparation and undertaking of this project. The main points discussed are the research questions, study design, ethical consideration, patient selection, recruitment, research and administration of data tools and the process of the patient interviews and assessment.

4.2 Study Aims

The research has two main aims. First to investigate the extent to which secondary prevention measures for CHD patients are managed in a contemporary West of Scotland setting and, second to evaluate a new healthcare model for the secondary prevention of CHD, with the care to be provided by a cardiac nurse specialist (CNS) working with patients and the healthcare team across the primary and secondary care interface.

4.3 Study objectives

- To identify the extent to which evidence based practice is applied to the management of patients with CHD.
- To examine the perceived health status of CHD patients and their motivation to make healthy lifestyle changes.
- To evaluate the impact of a cardiac nurse specialist (CNS) in the management of patients with CHD.

4.4 Research Questions

- What level of coronary risk factor documentation occurs in medical casenotes for those patients with known CHD?
- How effectively are patients with CHD managed in relation to reaching recommended target levels for coronary risk factors?
- What percentage of patients with CHD are prescribed evidence based prophylactic medication?
- What is the general health of patients with CHD as determined by the presence or absence of coronary risk factors?
- What are the perceptions of patients with regard to their current general health?
- How motivated are patients with CHD in making appropriate lifestyle changes?
- How effective is a specialist cardiac nurse (in Primary Care) in improving and managing CHD in those patients motivated to make healthy lifestyle changes?

4.5 Study Design

In an attempt to answer the research questions and achieve the study aims the project was designed and undertaken in two phases. A quantitative approach predominates in the design of the study. Phase one was undertaken in two parts. Phase I, part A was a retrospective descriptive survey of patient casenotes using a proforma for data collection. Phase I, part B was a prospective observational study, in the form of a self-completed postal questionnaire.

Phase II was a one-year randomised control intervention study. This incorporated both clinical and semi-structured interview methods for the intervention group and usual care for the control

group. The differences between both groups are discussed in detail in section 4.18-4.19. A cardiac nurse specialist, namely the researcher, delivered intervention. Time allocated for the study included study design, ethical approval, pre-testing, pilot work and the main randomised control trial (RCT). Therefore, it was anticipated that the work would be undertaken over a period of 36 months. A breakdown of the timetable of work and study design is given below in table 2.

Table 2 Time plan of study

	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	
Plan and Design																																					
Pilot work																																					
Phase I – part A																																					
Phase I – part B																																					
Phase II																																					
Data entry and analysis																																					
	Study undertaken over 36 months																																				

4.6 Sample Source

The sample was obtained from three general practices within the Strathkelvin Local Health Cooperative (SLHCC) located in the north of Glasgow. The practices cover an approximate total practice population of 25,000 patients.

4.7 Subject Number

A power analysis, undertaken by the Research and Development department at Stobhill Hospital, was used to estimate the number of patients needed for the RCT (Section 3.4). For the purposes of this thesis objective outcome measures such as cholesterol, blood pressure and weight were used for the power calculation as opposed to the subjective measures such as quality of life and symptom control scores. Following consultation with the hospital research and development department, a two-sided test at 80% power, with a significance level of 5% (alpha 0.05) using Microsoft Excel was used to establish the sample size required. Although the standard 90% power (Altman 1980) is known to be more sensitive it was felt that as only one researcher was undertaking the work a test at 80% would be more appropriate. Mean values for cholesterol, blood pressure and weight, obtained in phase I (part A) of the study (section 5.4) were used for the power calculation. Data from current epidemiological research and guidelines (Aspire Steering Group 1996; British Cardiac Society 1998; Wood *et al* 1997) were used to obtain the values for the minimal important difference (Diamond & Jeffries 2004). Results of the numbers produced are presented in table 3. The study was not powered to demonstrate a statistically significant difference in weight. Allowing for attrition rates, for example non respondents, a total of 45-50 patients was advised for each group.

Table 3 Numbers identified by means of power calculation for RCT

Variable	Mean	Standard Deviation	Minimal important difference	Estimated sample size per group
Cholesterol (mmol/l)	5.5	1.11	1	21
Systolic blood pressure (mmHg)	138.6	20.66	15	31
Diastolic blood pressure (mmHg)	79.6	10.76	10	20
Weight	77.8	14.98	10	37
Weight	77.8	14.98	5	142

Two sided test, at 80% power, with a significance value of 5% (alpha 0.05)

4.8 Sampling Procedure

All of the practices involved had General Practice Administration System for Scotland (GPASS). This is a computer database disease register, which originates from Information Services Department (ISD) Scotland. Patients are allocated standardised 'read codes' according to information contained in their medical records. Coding patients' records in this way allows practices to search for particular patient groups for clinical and audit purposes. In order to obtain the study sample for phase I, part A, a template incorporating the inclusion criteria for the project was compiled by the researcher using the appropriate read codes. The same inclusion criteria were also used for phase I part B and phase II of the research.

4.8.1 Inclusion criteria

The rationale for choosing this particular cohort of patients was based on the Joint British Cardiac Society Guidelines (British Cardiac Society 1998) which were based on the current evidence base for best practice. The inclusion criteria reflect the target population studied in these guidelines.

- Males and females
- Patients aged 75 years and under
- Patients with a diagnosis of angina
- Patients post myocardial infarction (MI)
- Patients post angioplasty
- Patients post coronary artery bypass grafting (CABG)

4.8.2 Exclusion criteria

For phase I part A the only exclusion criteria set was:

- No firm evidence of CHD

For phase I part B and phase II the following additional exclusion criteria existed:

- Terminally ill
- Mentally impaired (impairing patient to make own decision regarding care)
- Housebound
- Patients who the GP felt should not be contacted due to other circumstances

Having performed the search using the inclusion criteria, the GPASS software then generated a list of potentially suitable patients for the project (n=531). The researcher wished to compare targets in the study sample with targets from the guidelines,

Following completion of phase I, part A suitable patients were then selected for phase I, part B as discussed in section 4.14.1 (n=475). The decision was made to undertake the RCT at one GP practice alone; the rationale for this is discussed later in this chapter (Section 4.17). Patients for the RCT came from the original cohort of patients in phase I. Following completion of phase I, parts A and B at this practice patients were then assessed for their suitability to participate in the RCT (n=147).

4.9 Research Setting

Rooms were made available at each of the GP practices for the duration of the study. Data entry and analysis was carried out in the cardiology department at Stobhill Hospital.

4.10 Ethical Consideration

It was considered that in many ways the project was an extension of the cardiac rehabilitation process, focussing on education and health promotion. The main focus of the project was in achieving recommended target levels for blood pressure, cholesterol, weight and smoking. In addition the project focused on improving and maintaining diet, exercise and quality of life. Any changes in medication or blood samples obtained were in fact in accordance with the current guidelines and were the supposed best practice. Data collected were entered using unique identification numbers to ensure confidentiality for the patients. An application for ethical approval was prepared and submitted to the Local Research Ethics Committee (LREC) at Stobhill Hospital (appendix IV). Following assessment of the proposal, ethical approval was granted.

4.11 Informed Consent

Permission to review the patients' casenotes for phase I part A was sought and received from the relevant general practitioners at the practices. Permission was also granted to contact the patients for phase I part B and phase II. The issue of accessing patients casenotes without the patients prior permission was discussed with the LREC and in the context of the research this was not felt to be unethical providing the relevant general practitioners were in agreement.

Patients approached for phase I part B and phase II were fully informed from the outset regarding the nature of the study. They were assured of confidentiality and their right to withdraw from the study at any stage without it affecting their future treatment. Consent was obtained from the patients and general practitioners where appropriate. A written information sheet (appendix IV) and consent form (appendix IV) was prepared by the researcher to provide details of the study. Patients were reassured that the information collected would be available only to the researcher,

general practitioners and project supervisors and that anonymity would be ensured. It was explained that data collection during the study would be entered onto computer database and access, confidentiality and security maintained according to the regulations outlined under the Data Protection Act (Her Majesty's Stationery Office 1998).

4.12 Phase I – Preparation of data collection tools

Data collection tools for phase I of the study were compiled by the researcher and composed in the following formats; a proforma and a patient-completed questionnaire sent to the patients at home and completed by the patient.

4.13 Phase I – part A

4.13.1 Proforma

A proforma taking into account the content and layout of the medical casenotes was used to collect the appropriate data. This enabled the researcher to identify relevant data and provide a systematic and comprehensive method of data collection. Prior to piloting the proforma, the content was discussed with both junior and senior medical cardiology colleagues at the hospital. Information collected on the proforma (appendix V) included the following:

- Patient demographics
- Past medical history
- Prescribed medication
- CHD risk factors and date last documented

4.13.2 Pilot phase I – part A

The researcher undertook all research for the study. In order to reduce any personal bias, two separate trained health professionals (Research Nurse and GP) were asked to complete proformas on 10 casesheets previously reviewed by the researcher.

4.13.3 Evaluation of pilot phase I – part A

Time taken to review casesheets varied considerably dependent on the patients past medical history. Encouragingly, the data collected matched that of the data collected by the author. This reinforced the accuracy of data being collected but also demonstrated the proforma was a comprehensible data collection tool.

The main changes made to the proforma were the actual number of data collected. The first draft of the proforma was rather ambitious and perhaps had strayed slightly from the research questions. The initial draft had planned to examine details surrounding the primary diagnosis of CHD, which were not needed to answer the research questions. It also became evident that in order to answer the research questions the proforma should incorporate further fields regarding documentation of risk factors, which was done.

Forms for the data entry of this phase were also altered. Initially the author had anticipated coding answers. However, following discussion with the research and development department they suggested a more reliable method was to enter a “yes”, “no” response where possible. This was hoped to minimise errors in typing leading to errors in data.

Following changes to the proforma, as a result of the initial pilot, a further 10 casesheets were piloted with a revised proforma.

4.14 Phase I – part B

4.14.1 Postal Questionnaire

As described above, a postal questionnaire (appendix VII) was compiled by the researcher and designed for self-completion by the patients. The questionnaire incorporated both open and closed questions. In addition, likert scales (Parahoo 1997b) were incorporated to evaluate patients perceptions of health and motivation to make lifestyle changes.

The questionnaire was designed to collect data in the following categories of information:

- Patient details
- Past cardiological history
- Current angina symptoms and management
- Knowledge and understanding of CHD risk factors
- Perceived health and fitness
- Attitude to making healthy lifestyle changes

4.14.2 Pilot Phase I – part B

In order to test how robust such a questionnaire was, the tool was piloted on 20 random in-patients in the author's cardiology ward. Of interest to the author was not only how complete were the questionnaires returned but also how long had the questionnaire taken to answer. Time was taken to talk to each of the 20 patients and gather their suggestions for potential changes to be made.

4.14.3 Evaluation of pilot Phase I – part B

Patients participating in piloting the postal questionnaire were encouraged to give both negative and positive thoughts about the content and layout. Time taken to complete the questionnaire varied from 5-20 minutes with only two changes requiring to be made. The author had

inadvertently given patients the option to select, "don't know" to current smoking, which one of the patients had been amused to answer! The other change was regarding the wording of a question regarding hospital admissions. Patients liked the layout and understood the questions being asked of them. Only two patients did not fully complete the questionnaire and this was due to them being unaware of what their current medication was. Piloting the questionnaire in this manner proved invaluable and the appropriate changes were made prior to the main study being undertaken.

4.15 Phase I – Main Study

4.15.1 Administration of Proforma

Having identified patients from the GPASS system (n=531) a retrospective review of casenotes was undertaken by the author to examine current practice for management of CHD patients. On completion of the proforma patients were then categorised into one of three groups, low to high risk. This was done to allow the author to undertake further analysis regarding the motivation of patients. Data collected regarding the 'General Status of the Patient at Present' (see pg 171) were used to categorise patients. Those found not to be at the recommended target level for a particular coronary risk factor, or where recommended monitoring was not undertaken according to the recommended guidelines, were used as parameters. Patients were placed in the low risk group if they had 0 -1 of the above factors, for example, current smoker. Patients with 2 – 3 of the above factors, for example, current smoker, bloods not obtained in the last year and cholesterol 6.4mmol/l were placed in the medium risk group, and finally, high risk patients had to have 4 or more of the above factors. Of interest was whether or not those patients considered to be at higher risk in phase I (part A) were likely to respond to the questionnaire. By reviewing all the casenotes of those initially identified it ensured that only patients with a firm documentation of CHD (n=475) were then considered for not only the next stages of the study but also for data entry. Following review of each casenote, a preliminary decision utilising the exclusion criteria (Section 4.8.2) was made by the researcher to either include or exclude the patient in the phase I part B of the study.

The final decision regarding contacting the patients for the study was left with the GP, as it was felt that they were in the best position to know the suitability of their own patients. In order to do this individual GP lists were generated following casenote review. A standardised form (appendix VI) compiled by the CNS was given to GPs along with the patients casenotes. The relevant GP then intimated whether or not individual patients could be contacted. For those the

GP felt were unsuitable a written explanation was requested justifying their decision. Appropriate data were collected on those patients deemed unsuitable (n=99) for further contact in recognition of the need to account for all initial patients.

4.15.2 Administration of Postal Questionnaire

Having identified patients suitable for contact (n=376), this cohort of patients were then taken forward to the next stage of the study. This involved the completion of the self-completed postal questionnaire. Postal questionnaires were then sent to all suitable patients with a covering letter from their practice (appendix IV). The reason for the letter was to reassure patients that their GP was aware of the research and as such was supporting it. In addition to this, return stamped addressed envelopes were supplied to minimise the inconvenience to the patient and increase return of the questionnaires. A Microsoft Access computer database was set up by the researcher to record the number of questionnaires sent and returned.

Following completion and return of the questionnaires data were then entered into a Microsoft Access database. All data were entered however only those patients expressing an interest to make appropriate lifestyle changes were to be contacted for phase II. Patients responding to the questionnaire not wishing to make lifestyle changes were not taken any further in the study; however, if there was any aspect of their CHD management that required attention this was addressed with the relevant GP.

4.16 Phase II – preparation of data collection tools

The interview schedule (appendix VIII) for phase II compiled and completed by the researcher consisted of three data collection tools. A clinical assessment record was constructed to collect information; name, address, post code, date of birth, current medication and compliance, blood pressure, weight and height, smoking history, cholesterol and alcohol consumption. In addition to

the above record the schedule combined the use of the pre-validated SF36 (Ware *et al* 1992) as described in section 3.10.2. Semantic differential scales were also incorporated into the schedule to measure the patients' current symptoms of chest pain and dyspnoea, as described in section 3.9.3.

4.16.1 Pilot of Phase II data collection tools

Prior to commencing onto the main study of phase II data collection tools were again piloted on a random group of patients from our cardiology ward. Due to the volume of data being collected only 10 patients were asked to participate. The time taken by the author to complete the schedule was between 35 minutes and 1 hour and 20 minutes.

4.16.2 Changes to Interview Schedule following pilot

Only minor changes were made to the interview schedule which involved altering the layout of information being gathered in order to allow interviews to flow in a more logical order. Time taken to complete the interview schedule was significantly longer than had been expected and as such it was decided that one-hour should be allocated for the baseline visit proposed for the main study.

4.17 Pilot study of intervention

Following discussion with the practices it was agreed that a pilot of the intervention would be undertaken prior to the RCT. With consent from the GPs at Springfield Medical Practice a pilot study was carried out to assess the feasibility and practicality of the proposed intervention method. The anticipated time to undertake the pilot work was nine months. This time included

collecting data for phase I, parts A and B, in addition to making any necessary changes to the intervention method. Obviously due to the time constraints on the project there was a degree of overlap with both the pilot of the intervention method and main study for phase II (see table 2). Patients participating in the pilot of phase II received only intervention.

4.17.1 Evaluation of intervention method following pilot study

Undertaking a pilot of the intervention method allowed clearer insight into the time taken to undertake assessments in the setting of general practice, and also examine administration time. This proved an extremely valuable exercise as the researcher was able to document time taken to contact patients, make appointments and collect and action any changes as a result of either the assessment or blood results. Results for the pilot work of intervention were presented at the European Society of Cardiology and the abstract presented is displayed in appendix X.

4.18 Phase II Main study

Only the patients from Peel View Medical Practice were used for the RCT. The reason for this was due to time and travel constraints and also patients would be from a similar socio-economic spread. For phase II only motivated patients, as described in section 4.14.2 were selected.

Prior to contacting patients GPASS records were checked to ensure patients were still alive, this was decided to be the most accurate method of clarifying patient status.

Potential patients for phase II of the study were contacted regarding the proposed research by telephone. A brief description of the study and what the visit would entail was discussed. Telephone contact was chosen as it was thought to be more personal than a letter and also allowed for a mutually suitable appointment time to be made. This was hoped to reduce missed appointments and/or cancellations. The researcher undertook patient assessments.

4.18.1 Baseline Visit

All patients agreeing to participate in the RCT were invited into the practice for a baseline visit prior to randomisation. A dedicated room was made available at the general practice and appointments were structured in clinic format. One hour was allocated for each baseline visit, however this took into consideration time obtaining consent. On arrival to the interview room patients were introduced to the researcher and reassured that the assessment process was informal. Patients were offered a cup of tea or coffee prior to the assessment commencing and a note of the start time was recorded. Interview times varied between 35 minutes to 1 hour and 5 minutes. Patients participating in the study were given a full explanation of both the intervention and control arms of the study and were asked to give informed consent prior to commencement.

An individualised approach was taken in the management of patients. Patients were given a brief description of clinical measures (see section 4.17.2) to be undertaken along with the rationale

behind each. A detailed record of current medications were recorded and compared with that of their GPASS computer record. Patients were asked to provide details of their smoking history, alcohol consumption, exercise activity, and dietary habits. Any inactive medications were discussed and removed from the computer following discussion with the relevant GP. General health was measured using the SF36 (Section 3.10.2) and symptom control was measured using semantic differential scales. Time was allocated for the provision of information and education relating to the underlying causes of heart disease, the resultant symptoms of angina and breathlessness and its management, with time set aside for questions. The principles underlying motivational interviewing were used to guide conduction of the interviews and behavioural change (Prochaska *et al* 1992).

A verbal summary reinforcing points mentioned during the interview concluded the history taking aspect of the interview schedule. Individual specific risk factors, medical management and investigations were discussed. Patients were informed of possible medication changes and also aspects of diet, exercise, stress and smoking cessation intervention, which were thought to be beneficial. Patients decided on the areas of their lifestyle that they wished to concentrate on making changes to. Agreed goals were not necessarily set but patients were encouraged to consider relevant lifestyle changes. Where relevant, referral to health promotion initiatives such as smoking cessation, GP exercise referral and community dietician were offered to all patients. Patients were also encouraged to utilise the use of health promotion leaflets made available for the study.

4.18.2 Clinical Measures

In addition to collecting the information described above in section 4.17.1 appropriate clinical measurements were obtained in accordance with local and national guidelines (British Cardiac Society 1998).

4.18.3 Blood Pressure

Blood pressure was recorded towards the end of each assessment, as it was hoped patients would be more relaxed and a more realistic blood pressure would be obtained. The method of obtaining blood pressure was in accordance with the British Hypertension Society guidelines (Petrie *et al* 1986). A mercury sphygmomanometer was used for recording blood pressure, the sphygmomanometer was both validated and calibrated through the pharmacy department at Stobhill Hospital. Patients were seated, using their left arm (for consistency) at heart level an adult cuff selected according to arm circumference, small (9 x 18cm), medium (12 x 23cm) and large (15 x 33cm). The sphygmomanometer was placed on the desk and patients were instructed that two recordings would be obtained. The stethoscope was applied over the brachial artery just below the cuff and then the cuff was inflated to the point of occluding the radial pulse and then deflated at 2mm/s. The systolic measure was recorded as the emergence of sounds (Korotkov phase I) and the diastolic on the disappearance of sounds (Korotkov phase V), with blood pressure recorded to the nearest 2mmHg. A minimum of two blood pressures were recorded at each visit. Documentation of blood pressure was recorded in the interview schedule, patient's casesheets and hand held record.

4.18.4 Body Mass Index

A set of Salter mechanical scales were used solely for the purpose of the study, with regular calibration of the scales undertaken at the general practice to ensure accuracy of the recordings obtained. Weight was measured to the nearest 0.1kg with patient standing, outdoor clothing and shoes were removed. The patients height was recorded using a wall fitted height metre validated

at the general practice prior to the study commencing, this instrument was used throughout the duration of the baseline visits. Height was recorded in cm. Having obtained both recordings the patients BMI was then calculated as weight (kg) divided by height (m^2). Documentation of weight, height and BMI was recorded in the interview schedule, patients casesheets and hand held record.

4.18.5 Venous blood sampling

Prior to the joint guidelines (British Cardiac Society, British Hyperlipidaemia Association, British Hypertension Society, & endorsed by the British Diabetic Association 1998) being produced it was standard practice to obtain a full lipid profile, which required a fasting blood sample. The joint guidelines supported the collection of a random plasma serum cholesterol which did not require the patient to be fasted which was ultimately less inconvenient for patients attending. In addition to cholesterol random bloods were obtained for analysis of urea, creatinine, liver function, blood glucose and a full blood count. In the event of a patient being diabetic an HbA_{1c} was obtained. A venous blood sample was obtained in accordance with local Stobhill Hospital venepuncture standard. The preferred site for access was the ante-cubital fossa however if this was unsuccessful the cephalic vein at the dorsal arch of the hand was attempted. The chosen arm was supported and a tourniquet applied 2 – 4" above the chosen site of venepuncture to allow venous stasis and dilate the vein. Once the required samples of blood (10-13ml) were obtained into the appropriate biochemistry and haematology vacutainers the tourniquet was released and pressure applied over the puncture site for one minute, or until bleeding had stopped. Sharps were safely disposed of, bottles were labelled and bloods were then transported for analysis. All blood analyses were undertaken at Stobhill Hospital, using standardised protocols with internationally agreed quality assurance procedures.

4.18.6 Randomisation for phase II

The baseline visit was identical for all patients and randomisation of the patients took place only after these visits were concluded. A computer software programme (SPSS), was used to produce random numbers, which ensured equal groups, and that allocation was free from personal biases. To further remove any personal bias, following stratification for age and sex (due to the relatively small cohort of patients) a member of our hospital research and development department undertook the randomisation process.

Following randomisation, the patients were divided into the two arms of the study, namely intervention or control. Differences in the two arms are discussed below.

4.19 Intervention group

Patients randomised to the intervention group were assigned to nurse led care from the cardiac nurse specialist (CNS), namely the researcher. Following the baseline visit patients in the intervention group were then telephoned by the CNS to discuss subsequent management and inform them of the results of investigations undertaken during the baseline visit. Individual record cards were compiled by the CNS and sent out to the patients to allow them to document and follow progress (appendix IX). This was undertaken in an attempt to encourage the patients to take some responsibility for their health. Subsequent blood results or confirmation of changes in medical management were discussed by telephone within two to three days of assessment. A letter confirming results and changes made was sent to the patient within a week of the telephone conversation.

Scheduled appointments were arranged at 3, 6 and 9 months with a final assessment at 12 months. This totalled four formal appointments (inclusive of baseline visit) in which intervention from the

CNS could take place. Patients were notified that they could continue to see their own GP and other members of the practice team as normal.

The format of the follow up visits was again a structured clinic appointment collecting relevant information on individual progress with risk factors, medication and symptom control. In line with the Joint British Guidelines (British Cardiac Society 1998) clinical measurements of blood pressure, weight and cholesterol were obtained. Quality of life using the SF36 was measured at baseline, 6 months and one year.

In addition to collecting the relevant data for the RCT, patients randomised to intervention were given education and support from the CNS.

The main aims of the education were to:

- Improve patients understanding of the process of CHD
- Discuss what risk factors are and how to address them
- Highlight the relationship risk factors have on CHD
- Improve patients understanding of their medication and discuss issues of compliance
- Discuss symptom control and management
- Ensure patients were aware of the importance of recognising when their symptoms required urgent hospital attention and admission

The main focus of the support mechanism involved:

- Encouraging patients to make appropriate healthy lifestyle changes
- Facilitating contact to appropriate smoking cessation interventions
- Facilitating contact to appropriate weight management interventions
- Facilitating contact to the GP Exercise Referral Scheme
- Referral to their GP if indicated
- Referral to secondary care if indicated

- Access to contact – patients could phone the CNS to discuss any aspects of the study and/or their CHD management

4.20 Control group

Following the baseline interviews a written summary of the assessment and decisions made was documented in the interview schedule and the patients' medical casenotes. Patients in the control group were contacted by telephone by the CNS with the relevant blood results and their individual GPs were alerted to the findings of the baseline visit. For example GPs were aware of a patients elevated cholesterol or blood pressure measurement. Patients were advised to seek advice from their GP regarding elevated findings as it was in the patients best interest to address these areas. It was also deemed unethical to ignore these factors.

Following this interaction from the CNS patients received no further interaction with the CNS until the final visit for the RCT at 12 months. Patients in the control group received only usual care given by their GP and practice team. Again patients were informed during the baseline visit that they should continue to see their GP and other health care professionals as normal.

4.21 Data Management and Analysis

All data collected for each patient were entered onto Microsoft Access data forms compiled by the author, and stored electronically. Data analysis was undertaken using both Microsoft Access and Minitab. Data collected, stored and extracted for presentation were managed in accordance with the data protection act (HMSO 1998). Further information regarding the data collected and methods of analyses are detailed below.

4.21.1 Phase I

Information collected for phase I combined both discrete and continuous variables and produced data on 475 patients.

4.21.2 Phase II

The fundamental issues to be dealt with in analysing the data collected over the study period was based on the following key questions of interest:

- Are the two groups comparable in terms of their risk factors at baseline
- Is there a significant difference between the intervention and control groups in terms of the changes in risk factors from baseline to 12month follow up
- Is there a significant difference between the intervention and control groups in terms of symptoms, prophylactic medication and health related quality of life.

The primary hypothesis that there will be a significant difference between the intervention and control groups was tested using students t test and chi-square (Diamond & Jeffries 2004).

Following discussion with a statistician (Harper Gilmour, University of Glasgow), it was agreed that additional analysis on an intention to treat basis could be undertaken. This involved analysing

data on those patients who failed to complete the 12month follow up as people who made no change.

4.22 Data Analysis

This next section will explore the type of data being produced in the study and examine methods of data analysis.

4.22.1 Variables

It is important to ascertain what data are available for analysis. The main types of data produced are called variables (Diamond & Jeffries 2004). There are numerous variables of interest that can be studied and to ease the process variables can be separated into two main groups, continuous and discrete. Continuous variables for example, “cholesterol level” can potentially adopt any value within a given range, and discrete variables for example “gender – male/female”, have no numerical value. Discrete variables may be assigned a value such as “very poor health = 5” but the value of the numbers are irrelevant.

4.22.2 Summary Statistics

Averages and percentiles

There are three main averages, which we commonly use to analyse and present data (Swinscow); *Mean*; to calculate the mean we add together all the values of the observations and divide by the sample size. The mean is probably the most frequently used measure of the average. The disadvantage of using the mean is that it is dependent on all the values and therefore is sensitive to outliers (points well outside the main body of data).

In statistical terminology the mean is calculated as follows:

$$\text{Mean} = \frac{\sum x}{n}$$

Mode; the mode is the value, which occurs most frequently in the sample. If there are two values for which this is the case then the distribution is said to be bimodal. *Median*; in contrast to the mean and mode, the median is the middle observation in the dataset. The data require to be ordered to calculate the median, however, all the data values are not required. To calculate the median on an odd dataset simply requires adding the two mid points and dividing by two. The formula for calculating the median is as follows:

$$\text{Median} = \frac{n+1}{2} \text{ th observation}$$

Dispersion

In order to know the distribution of the data we can employ further measures namely the range, the interquartile range and the standard deviation. These measures allow us to further analyse the data and examine how evenly or otherwise the data are distributed. The range reports the lowest and highest values of the dataset. Again, like the median the range is very sensitive to outliers and can therefore be somewhat deceptive.

Interquartile range

Perhaps a better description of the variance of data is to measure the interquartile range. To calculate this we must know the median, the lower quartile represents the midpoint between the median and the lowest value. The upper quartile represents the midpoint between median and the highest value. The remaining portion of data is described as the interquartile range (mid-spread). Because the interquartile range does not use all the observations in the dataset it is not so affected

by outliers, as is therefore more robust than using the standard deviation. The interquartile range should be used as a measure of spread when the median is being used as a measure of average.

Standard deviation

The standard deviation (SD) is most commonly used where data are not too skewed or when as in the interquartile range, where the mean is being used as a measure of the average. The standard deviation measures the average amount by which all the values deviate from the mean. It informs us about the size of the difference between a particular observation and the mean (residuals). Standard deviation is calculated as the square root of the sum of the squared residuals. The larger the standard deviation, the greater is the spread of the data.

4.22.3 Normal distribution

Data can be described as either normally distributed, or skewed. Data that are normally distributed when displayed on a histogram or graph are symmetrical and are distributed in a ‘bell-shape’ this reveals the mean and median are in fact equal. On the other hand data that are skewed indicates the values of the mean and median are different due to the mean being affected by extreme values found in the dataset. Data can be positively or negatively skewed. Positively skewed data are concentrated at the lower end of the range and conversely negatively skewed data are concentrated at the higher end of the range. The normal distribution is the most important statistical distribution (Diamond & Jeffries 2004).

4.22.4 Hypothesis

Normal distribution of data helps us evaluate the probability of something happening. This can be taken further by introducing a study hypothesis. For the purpose of phase II of the study we are interested in the whether or not the specialist cardiac nurse is better than usual care for the patients in managing CHD risk factors. Most studies are designed to prove a hypothesis held by the

researcher, firstly we must intimate what we expect to happen if the statement is true. This is known as the null hypothesis or H_0 .

4.22.5 Intention to Treat

This method of analysis by intention to treat is an extremely paramount issue in this study. Generally, in clinical trials like this, it is perhaps somewhat expected that not all of the patients will comply with the original protocol. Some may for whatever reason fail to attend an appointment or even stop attending entirely. The approach is used in this trial so far limits the analysis to include only those patients who complied ie those patients who attended all appointments, and omits those who did not.

The general rule in clinical trials is that treatment groups should be compared as they were formed by randomisation, regardless of what happens to the patients throughout the trial. In doing so, the patients are then analysed not according to how they were treated, but rather according to how it was intended they should be treated.

These two methods can very often produce different conclusions, mainly due to the fact that they are answering different questions.

Furthermore, accounting for all patients involved in the study will undoubtedly avoid possible bias. Consequently it is crucial to carry out the analysis using the 'intention to treat' approach in addition to the method already applied to the data, to ensure accurate results and conclusions are reached.

4.22.6 Presentation of results

Results for this thesis will be presented using a number of different methods and will in part be generated with the aid of a computer software programme, namely Minitab (Minitab statistical

software 2005). Tables, figures, pie charts, box plots and histograms will be used to present the data as appropriate.

5.0 Results – Phase I

5.1 Introduction

In this chapter results for phase I are presented in two parts; A and B. Data were collected in order to answer the following research questions:

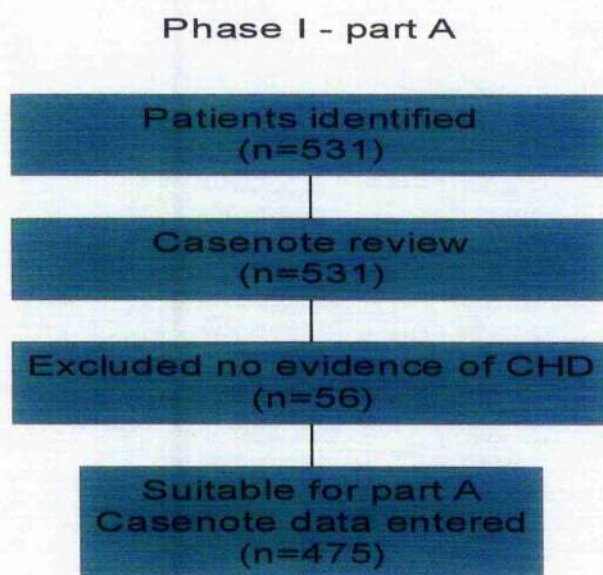
Part A

- What level of coronary risk factor documentation occurs in medical casenotes for those patients with known CHD?
- How effectively are patients with CHD managed in relation to reaching recommended target levels for coronary risk factors?
- What percentage of patients with CHD are prescribed evidence based prophylactic medication?
- What is the general health of patients with CHD as determined by the presence or absence of coronary risk factors?

5.2 Patient selection

Casenotes of patients with a diagnosis of IHD, from three general practices in the North Glasgow area were studied. The total practice population for the three practices is approximately 23,700.

Figure 1 methods employed in the identification and selection of patient numbers for Phase I - part A



As highlighted in figure 1, following casenote review (Section 4.13.1) 10.5% (n=56) were found to have no firm diagnosis of IHD, and were excluded from data entry. Results herein are therefore based on 475 patients unless otherwise stated.

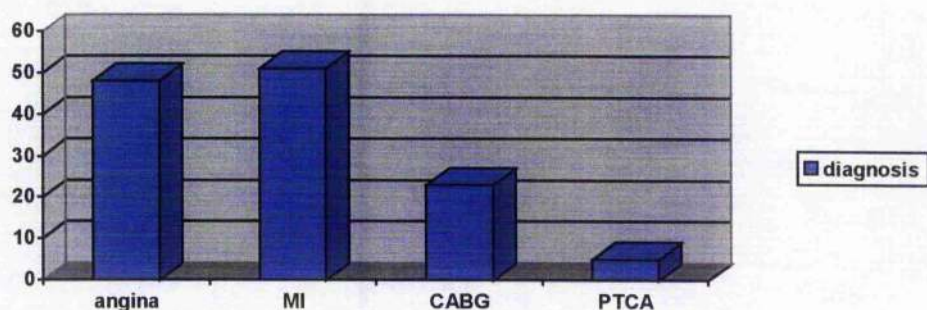
5.2.1 Age and gender

In the overall study population there were more males, 67% (n=319) than females 33% (n=156), with males on average being younger than females (mean 63yrs+/- SD 7.9 (m) versus mean 65yrs +/- SD 7.9 (f)). The age range was 36 to 75 years.

5.3 Past Medical History

Data were gathered from casenotes to explore the nature of relevant past medical history and identify what percentage of patients had previously sustained a cardiac event ie MI. Figure 2 presents data for patients found to have one or more of the pre-defined IHD criteria.

Figure 2 Percentage of patients with documentation of one or more IHD diagnosis, as retrieved from casenote analysis

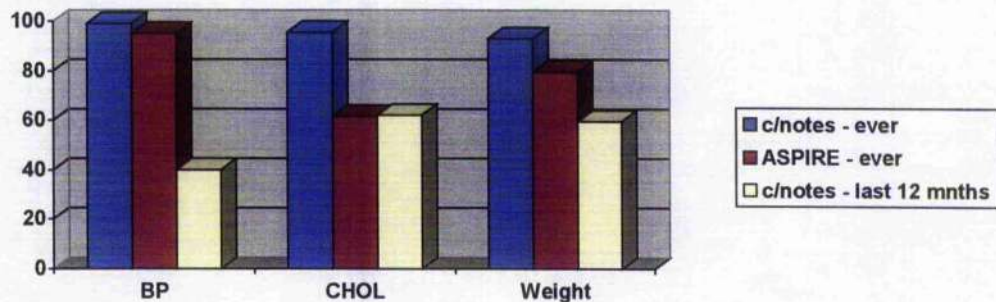


Only 5% of patients had undergone PTCA, which is likely to be a reflection of management at this time.

5.4 Risk factors

The last recorded measurement for each of the risk factors being examined was obtained from casenotes. Data were examined to evaluate how frequently patients had their risk factors recorded, in accordance with current guidelines and a comparison made with results reported in the ASPIRE survey. Percentages are used to present the data gathered (figure 3).

Figure 3 Comparison of the % of patients found in ASPIRE and in the current study with documentation or coronary risk factors



Practices achieved higher rates of risk factor documentation in comparison to findings from ASPIRE, however examining those risk factors obtained within the last 12 months show that these measurements are not being routinely updated in accordance with current guidelines, ie annual recording.

Data were then analysed to determine what percentage of patients achieved recommended target levels in accordance with current guidelines. Results are presented as mean measurements, actual numbers and percentages (table 4).

Table 4 Summary statistics for modifiable risk factors Phase I part A

Variable	Mean (SD)	Range	Target	n above target (%)
SBPmmHg	138.57 (99)	80-200	≤ 140	185 (39.3)
DBPmmHg	79.18 (10.9)	50-130	≤ 85	114 (24)
Total chol mmol/l	5.45 (1.11)	2.5-9.7	≤ 5.2	259 (57)
BMI	27.85 (4.84)	15-50	≤ 25	280 (72.5)

Results reveal a lower percentage of patients, 61% (n=290) achieve systolic blood pressure target (≤ 140 mmHg) compared with 76% (n=361) achieving diastolic blood pressure target (≤ 85 mmHg). Both mean cholesterol and BMI were recorded above target level, which was echoed in the percentages achieving target overall, 45.5% (n=216) and 27.5% (n=106) respectively. Although weight was routinely documented in the casenotes, 93% (n=443), height was not available for 19% (n=89), which is essential for calculating BMI.

Assessment of smoking status ever recorded revealed two percent (n=10) of patients had no documentation of smoking habit. Of the 98% of notes with smoking status recorded 23.5% (n=109) were current smokers, 40.5% (n=188) ex-smokers and 36% (n=168) life long non-smokers. ASPIRE results reported a total of 88% had smoking status ever recorded.

Findings show that smoking status is well documented, with higher percentage being recorded within practices compared with ASPIRE. Written advice regarding smoking cessation was not formally collected, however, it was observed by the author that casenote documentation regarding this was very infrequent.

5.5 Prophylactic evidence based medication

Data obtained from prescribing summaries were used to determine the extent to which patients were prescribed the recommended evidence based coronary medications, namely Aspirin, Beta Blocker and Statin.

This revealed a total of 77.5% (n=368) of patients were prescribed Aspirin, 48% (n=228) Beta Blocker and 56% (n=266) Statin. Information regarding patients buying 'over the counter' (OTC) Aspirin and for those whom medications were contraindicated for was not routinely available.

Of the post MI patients (n=242), 84% (n=203), 46.3% (n=112) and 61.6% (n=149) were prescribed Aspirin, Beta Blocker and Statin respectively, with 24% (n=58) post MI patients being prescribed all three. Of the non MI patients (n=233), 40% (n=93) were prescribed both Aspirin and Statin.

From these results there is clear evidence that both individual prescribing is sub-optimal for the overall group and the combined prescribing of all recommended prophylactic evidence based medications is very poor.

5.6 Part B

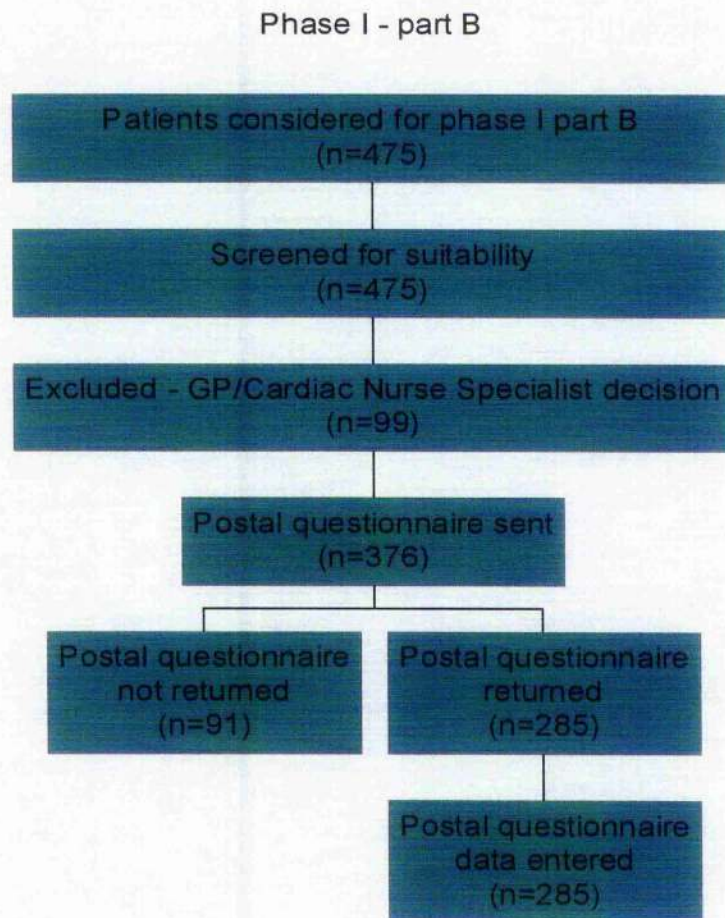
- What are the perceptions of patients with regard to their current general health?
- How motivated are patients with CHD in making appropriate lifestyle changes?

5.7 Patient selection

Patients selected for phase I part B were obtained from the original cohort of patients identified at the outset of the study. Following consultation with GPs (see 4.14.1), 99 were deemed unsuitable for the self completed postal questionnaire – questionnaire A (see appendix VII), this left 376 (79% of the original cohort) patients eligible for participation in part B.

Part B

Figure 4 Methods employed in identification and selection of patient numbers for Phase I - part B



Of the 76% (n=285) responding to questionnaire A, 67% were male, and 33% female, mean age 63yrs +/- SD 8.0. Results herein are based on the 285 responding to postal questionnaire unless otherwise stated.

5.8 Questionnaire responses

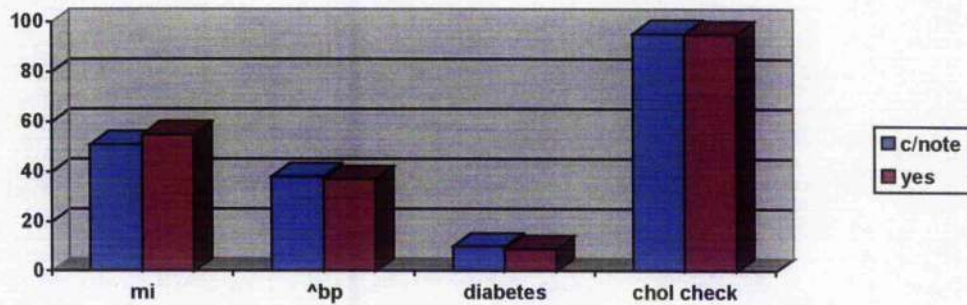
Patients were asked to answer questions regarding past and/or current medical history, in relation to heart disease, eg “Have you ever had a heart attack?”, “Yes”, “No” or “Don’t Know”

Fifty five percent (n=156) of patients recorded having sustained an MI in the past with 15% (n=42) stating they “didn’t know”. 37% (n=106) reported having hypertension with 16% (n=44) stating “didn’t know”. 9% (n=26) reported having a diagnosis of diabetes, with 6% (n=16) stating “didn’t know”.

Fifteen percent (n=43) admitted to being current smokers. 95% (n=265) of patients reported having their cholesterol checked in the past, with 46% (n=130) stating they had knowledge of the “result”. Of those aware of the result, answers ranged from ‘have no cholesterol!’ to 7.6mmol/l.

In order to assess the patients knowledge of their past history it was important to compare this with what was documented in the casenotes. The findings of this analysis are displayed as percentages in figure 5. It is evident from this that patients on the whole are well informed about their health.

Figure 5 Comparison of patient % with documentation of diagnosis in casenote retrieval versus patients own reporting in postal questionnaire



5.9 Medication

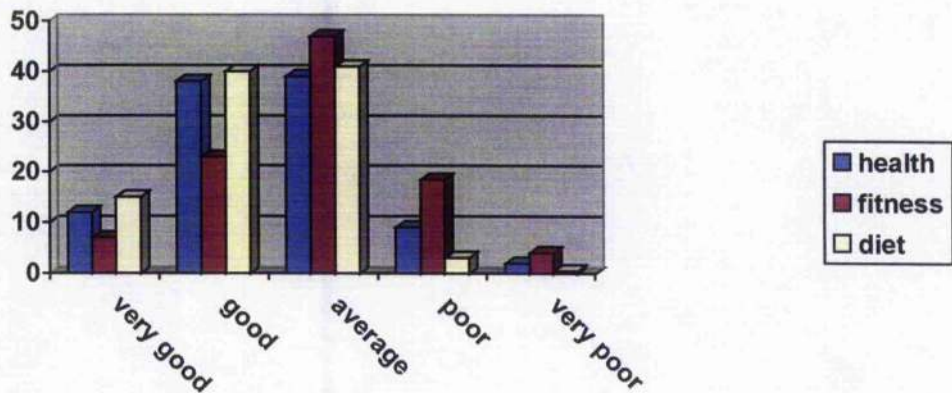
Patients were asked to give a list of all the medication they were currently taking.

78% (n=223) reported taking Aspirin, compared with 77.5% (n=368/475) found on casenote review. This would suggest that the majority of patients were prescribed their aspirin even if they bought it 'over the counter'. 15% (n=44) admitted to occasionally missing their medication however, only 3% (n=8) stated that they found taking medication difficult.

5.10 Perceptions of general health and fitness

Patients were asked to rate their perceived level of general health, fitness and diet on a five-point scale. The responses are illustrated in figure six.

Figure 6 Distributions of responses of patients perceptions of level of health, fitness and diet



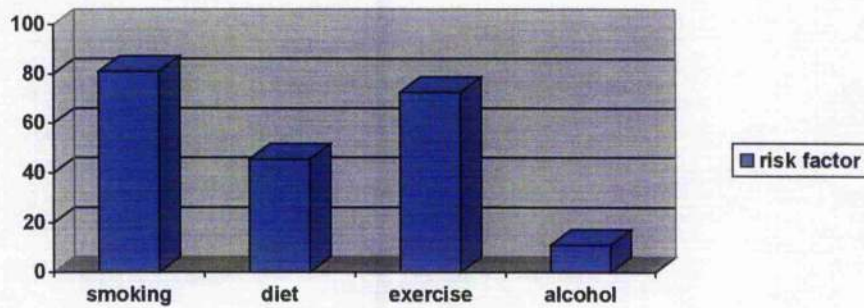
As can be seen patients were more likely to rate aspects of their health as average or above average (good-very good).

5.11 Motivation to change

Patients were asked whether or not they felt they could improve aspects of their lifestyle.

All patients responded to this question regarding lifestyle changes, 66% (n=189) indicated they felt they could improve aspects of their lifestyle. A further 9.5% (n=27) indicated they had 'never thought about it'. Patients were then asked what aspects of their lifestyle they could change, with particular relevance to coronary risk factors. Patients were encouraged to tick all relevant fields; figure seven displays the frequency of all the responses given for this particular question.

Figure 7 Percentage of patients responding to postal questionnaire indicating areas of lifestyle they wish to address

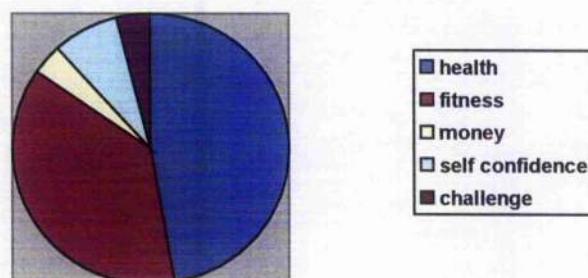


As illustrated 81% (n=35) of current smokers identified this as an area for improvement with exercise being the next highest priority identified at 72.5% (n=137).

Of the 96 patients not wishing to make lifestyle changes, 72% (n=69) reported that their 'lifestyle was healthy'.

Patient were asked why they wished to make lifestyle changes, from a list of reasons selected by the author, again, patients were encouraged to tick all relevant fields. Figure eight displays the frequency of all of the responses given for this particular question.

Figure 8 Actual numbers of patients reporting reasons for wishing to make lifestyle changes

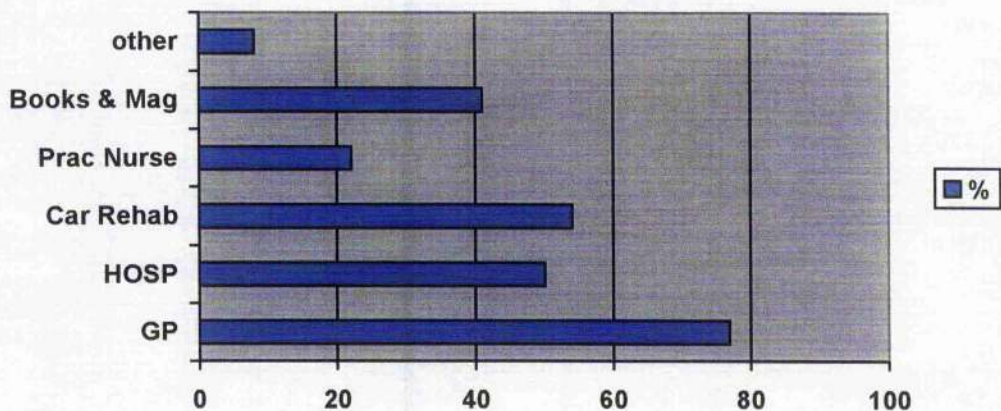


As can be seen, health and fitness were most frequently selected, 81.5% (n=154) and 64.5% (n=122) respectively.

5.12 Education

Patients were asked if they had ever received education about healthy living or heart disease, and if so, where this information came from (figure 9).

Figure 9 Indicates where patients source their educational information, data are presented as % and patients may have identified more than one area



A total of 77% patients (n=219) reported they had previously received or obtained information regarding healthy living or heart disease. Of this group 76.7% (n=168) received education from their general practitioner, 22% (n=49) received information from the practice nurse.

For the patients indicating they had received their education from other sources, they were asked to state examples. Answers for this included 'TV', 'video', 'internet', 'Hospital Consultant' and 'the wife'.

5.13 Conclusion

The data produced for phase I, parts A and B present an overview of how CHD patients are managed in accordance with their documentation and management of modifiable risk factors and implementation of prophylactic evidence based medication. It also gives us an insight into how knowledgeable patients are regarding their health and how motivated they are to making appropriate changes. The following key points summarise the conclusions for phase I.

Part A

- Documentation and management of modifiable risk factors, was superior to findings in Aspire, however, remains sub-optimal
- Implementation of prophylactic evidence based medication was also found to be sub-optimal with regard to achieving risk factor targets and initiating all appropriate therapies

Part B

- Patients who are perceived to require the most intervention are less likely to respond to the offer of help
- Patients were well informed of their past and present medical history and had received or obtained relevant education about their health
- The majority of patients were motivated to make changes to their health where it was deemed necessary

6.0 Results – Phase II

6.1 Introduction

In this chapter the results for phase II are presented. Data were collected in order to answer the following research question:

- How effective is a specialist cardiac nurse (in Primary Care) in improving CHD risk factors, and what is the impact of the specialist cardiac nurse in the management of these patients?

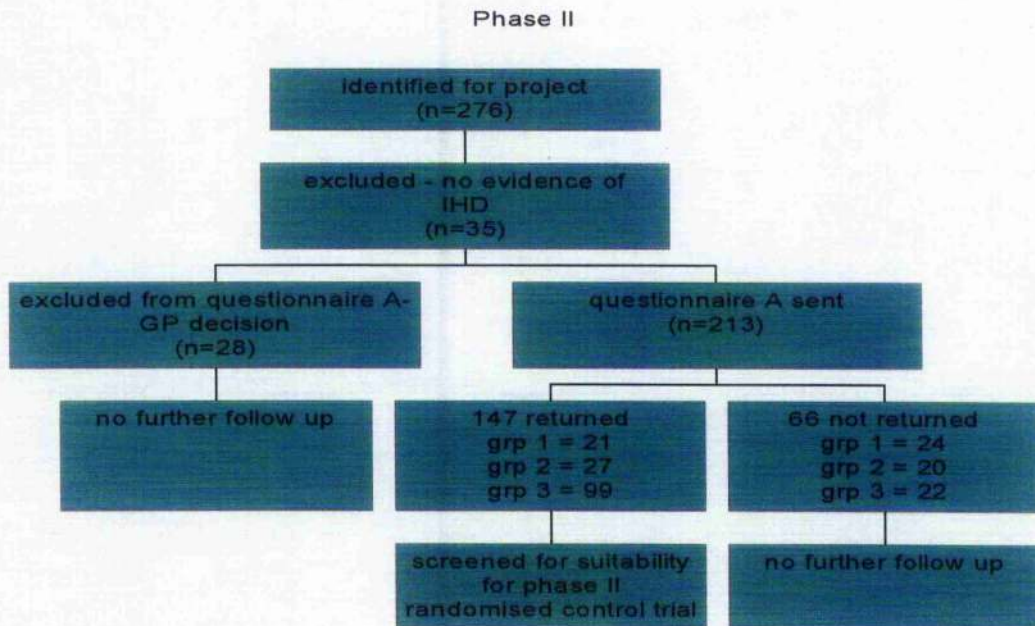
6.2 Patient selection

Patients for phase II of the project were obtained from one of the three general practices involved in phase I (Section 4.17). Figure 10 illustrates the number of patients identified for phase II of the project, and their subsequent follow up. Patients from this practice were a sub-group of the original cohort of patients in phase I and as such data gathered from casenote review and postal questionnaire (questionnaire A) for this group are reported as part of the total population of phase I (chapter 5).

276 patients were identified from this practice using the pre-defined IHD criteria (Section 4.7.1). A total of 35 were excluded from data entry (figure 10). Of the population being studied for phase II, there were more males, 61% (n=148) than females 39% (n=93), with males on average

being younger than females (mean 63yrs+/- SD 8.5 (m) versus mean 65yrs +/- SD 8.7 (f)). The age range was 36 to 75 years.

Figure 10 Methods employed in identification and follow up of patient numbers for Phase II



12.6% (n=35) were found to have no evidence of IHD and as such their data were not entered. This left 241 (87.4% of the original cohort) patients eligible for participation in phase II – randomised control trial, and as such their casenote data were entered.

6.3 Questionnaire A response rate

A further 10% (n=28) were excluded from progressing further in the project, as they fitted into one or more of the pre-defined exclusion criteria (Section 4.14.1). Questionnaire A was therefore administered as described in figure 10 to 77% (n=213) patients.

A response rate of 69% (n=147) was achieved from questionnaire A at this practice. Table 5 below presents the absolute numbers of patients responding and failing to return questionnaires

and how this correlates to the risk groups (Section 4.14.1) patients were allocated following casenote review.

Table 5 Postal questionnaire response in actual numbers

Questionnaire A	Risk Group (n=)		
	One	Two	Three
Questionnaires not returned (n= 66)	24	20	22
Questionnaires returned (n= 147)	21	27	99
Total	45	47	121

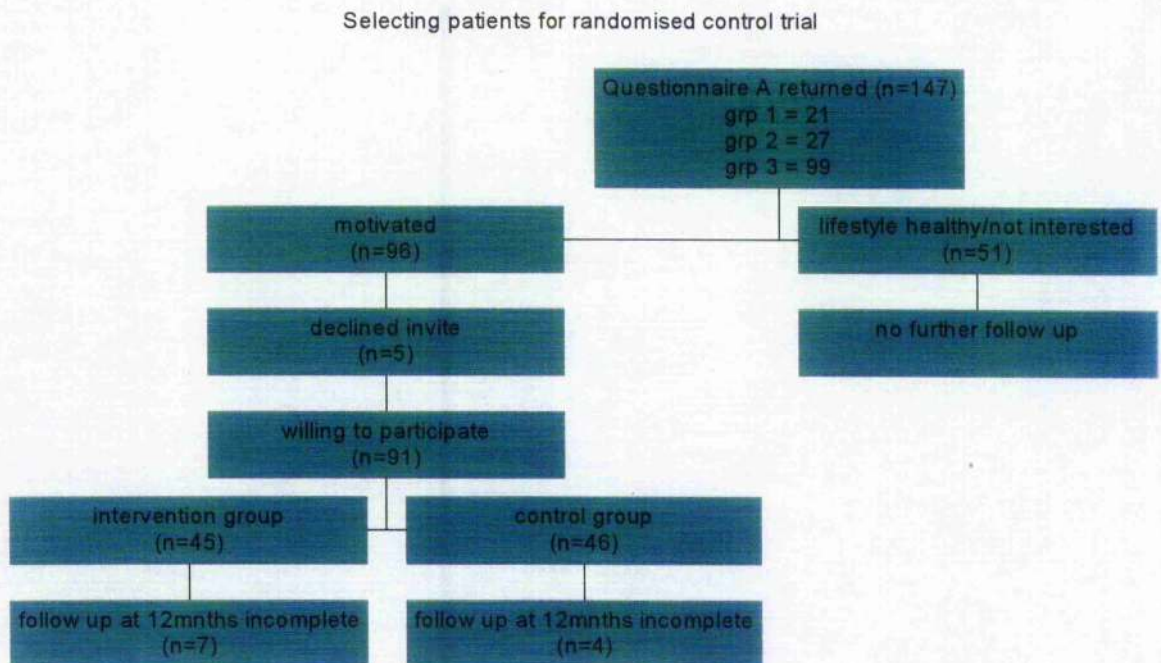
Chi-Square at 5% significance level with 2 degrees of freedom was applied to the data

A significant difference ($p=0.000$) was found between the groups, and it is therefore likely that more patients in the higher risk groups, ie Group One did not return the questionnaire A.

6.4 Patient selection

Data for patients responding to questionnaire A ($n=147$) were then entered and analysed to assess the suitability of these patients to progress to the RCT. Figure 11 illustrates the actual numbers of patients screened for suitability for the RCT and their subsequent follow up.

FIGURE 11 METHODS EMPLOYED IN THE IDENTIFICATION AND SELECTION OF PATIENT
NUMBERS FOR PHASE II - RANDOMISED CONTROL TRIAL



As figure 11 illustrates, 34.7% (n=51) indicated in the questionnaire that either their lifestyle was healthy or they were not interested in improving aspects of their lifestyle. Data from the postal questionnaire were entered for this group however there was no further follow up. This left 65.3% (n=96) of those responding to the questionnaire who were deemed suitable for inclusion into the RCT.

Five patients declined the invitation to attend for the project and were not followed up further. This left 91 patients who were invited to participate in phase II of the project (RCT). Following randomisation (4.17), 45 were allocated to intervention and 46 to control.

6.5 Summary of baseline characteristics for randomised control trial

Baseline characteristics for the two groups are summarised in table 6. In order to assess the two groups at baseline a two sample t test was undertaken to ensure there were no significant differences between the groups.

Table 6 Control and intervention groups at baseline

VARIABLE	CONTROL GROUP	INTERVENTION GROUP	p value
Number of patients	46	45	NS
Males	26	26	NS
Females	20	19	NS
Age (years)	62.5	62.1	0.725
Range	(42-75)	(45-75)	
SBPmmHg	136.54	136.71	0.973
Range	(85-190)	(95-200)	
DBPmmHg	81.54	81.56	0.996
Range	(60-105)	(55-110)	
Weight(kg)	80.2	79.4	0.797
	(49-118)	(40-118)	
BMI(kg/m²)	28.7	27.9	0.862
	(21.7-40.1)	(17-40.5)	
Number of smokers	10	10	0.986
Total cholesterol mmol/l	5.26	5.35	0.708
Range	(3.7-7.8)	(3.6-8.7)	
Alcohol – numbers in each category			
(categories 1-4)	39	37	NS
(categories 5-8)	7	8	

Table 6 clearly demonstrates that the two groups were extremely well matched and no statistically significant differences were found in any of the parameters being examined.

Absolute numbers and percentages were used to examine how comparable the two groups were at baseline with regard to current prescribed prophylactic medication and risk factor targets (table 7). It is of note that when analysing cholesterol levels, both 5.2mmol/l and 5.0mmol/l have been examined, this is due to a change in the guidelines which took place during the course of the project.

Table 7 Baseline characteristics for intervention and control in relation to risk factor targets and prescribing

Variable	Intervention n=45		Control n=46		χ^2 test
	n =	(%)	n =	(%)	p value
Aspirin	42	(93)	42	(91)	0.716
Beta Blocker	23	(51)	22	(48)	0.754
Statin	29	(64)	26	(57)	0.44
SBP \leq 140	27	(60)	26	(57)	0.737
DBP \leq 85	30	(66)	36	(78)	0.215
BP \leq 140/85	24	(53)	24	(52)	0.912
BMI \leq 25	13	(29)	9	(20)	0.299
Current smoker	10	(22)	10	(22)	0.956
TC \leq 5.2mmol/l	27	(60)	19	(41)	0.075
TC \leq 5.0mmol/l	20	(44)	16	(35)	0.346
Alcohol					
Males > 28units/wk	3	(6)	1	(2)	0.296
Females > 21units/wk	0	(0)	0	(0)	NA

Chi-square at 5% significance level, with 1 degree of freedom was used to calculate statistical difference.

Again, it is clear from table 7 that there are no statistically significant differences between the groups. It is observed though that a higher percentage of patients in the intervention group have cholesterol level at target.

Table 8 illustrates the total numbers and percentages found in the two groups with IHD diagnosis. Patients may indeed have had one or more of the CHD diagnoses being examined.

Table 8 Breakdown of % of patients documented in both groups with one or more IHD diagnosis

	Intervention		Control		χ^2
Diagnosis	n=	(%)	n=	(%)	p value
Angina	16	(35.5)	24	(52)	0.110
MI	24	(53)	24	(52)	0.912
CABG	8	(18)	9	(19.5)	0.827

Chi-Square tests at 5% significance level, with 1 degree of freedom were again adopted to obtain statistical significance

Results demonstrate that there are no significant differences between the two groups at baseline and reinforces how well the two groups are matched at baseline.

6.6 Follow up of patients

Patients in the intervention group were invited for assessment every three months, attending for a potential of five visits in total, ie baseline, 3, 6, 9 and 12 months. Patients in the control group were invited for a potential two visits.

A total of 11 patients were not able to complete the 12 month assessment, however, their follow up status was identified as presented in figure 12.

Figure 12 Details outcome of patients unable to complete 12 month RCT

INTERVENTION (n= 7)	CONTROL (n= 4)
<ul style="list-style-type: none"> • 2 DIED (1 FROM CARDIAC CAUSE) • 2 MOVED FROM AREA • 1 ALIVE BUT UNCONTACTABLE • 1 TERMINAL ILLNESS • 1 DECLINED FOLLOW UP FOR PERSONAL REASONS 	<ul style="list-style-type: none"> • 2 DIED • 2 MOVED FROM AREA • 1 LOST TO FOLLOW UP

changes over the 12months, these patients data were removed from analysis.

6.7 Changes from baseline to 12months

A total of 84.5% (n=38) and 91.3% (n=42) completed the 12 months for intervention and control respectively. Basic descriptive summary statistics and two sample t tests were undertaken to examine mean differences between baseline and 12 month follow up for the two groups. Intervention and control were compared using two sample t tests. Table 9 displays the results of mean changes and any statistical significance found within variables.

Table 9 Illustrates the changes found between the two groups at 12 months

VARIABLE	INTERVENTION	CONTROL	p value
Number of patients	38	42	NS
Males	26	26	NS
Females	19	20	NS
Age (years)	62	63	NS
Range	(45-75)	(42-75)	

Variable	Mean difference between baseline and 12months Intervention Control		95% Confidence Interval for Mean Difference (Intervention – Control)	p value
SBPmmHg	17.97	5.43	(3.22, 21.87)	0.009
DBPmmHg	13.13	6.36	(1.98, 11.57)	0.006
Weight (KG)	0.16	- 0.06	(-1.36, 1.81)	0.782
BMI	0.14	0.01	(-0.45, 0.72)	0.643
SMOKING (no. of cigs)	1.74	-1.07	(0.922, 4.70)	0.004
Total cholesterol mmol/l	0.74	0.19	(-0.10, 1.01)	0.002

Two sample t tests were undertaken to compare the difference between intervention and control findings at 12 months

Results reveal that changes in the main modifiable coronary risk factors, namely, blood pressure ($p < 0.00$), and cholesterol ($p=0.018$) show statistically significant improvements within the intervention group. Although no statistical significance is observed in smoking cessation the total number of cigarettes smoked between the two groups showed a statistically significant ($p=0.004$) reduction in the number of cigarettes smoked in the intervention group.

6.8 Percentage of patients reaching target levels in accordance with current guidelines

In addition to examining mean changes between the two study groups, it was also of importance to assess if a higher percentage of patients in the intervention group reached target levels recommended in current guidelines. As previously mentioned, the cholesterol target changed during the project and as such the author has chosen to use the new cholesterol target of 5.0mmol/l for the purposes of analysis. Figure 14 illustrate the percentages of patients in both the intervention and control group reaching target both at baseline and 12 months.

Figure 13 Percentage of patients in both groups reaching target blood pressure at 0 and 12 months

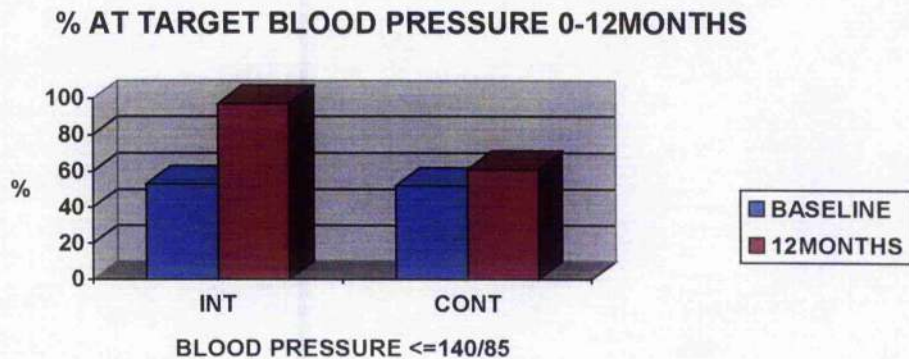


Figure 14 Percentage of patients in both groups reaching target cholesterol at 0 and 12 months

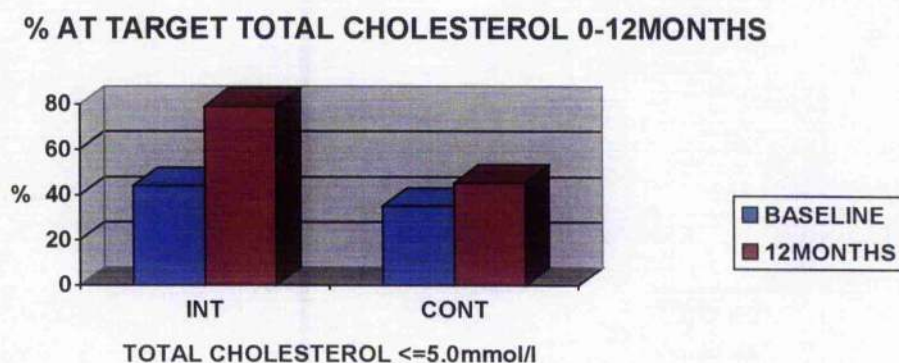
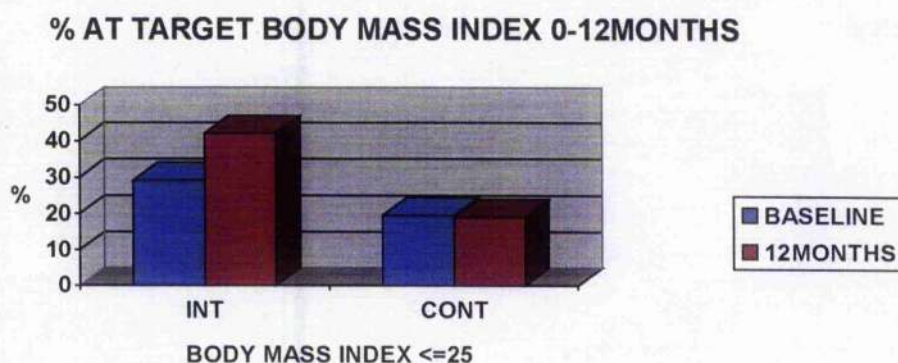


Figure 15 Percentage of patients in both groups reaching target BMI at 0 and 12 months



It is evident from figures 13-15 that in all variables a higher percentage of patients reach target in the intervention group than in the study group.

In order to examine this further Chi-Square tests at 5% significance level, with 1 degree of freedom were undertaken on each variable to obtain statistical significance (table 10).

Table 10 Demonstrates statistical significance found between groups at 0 and 12 months

Variable	<i>p</i> value	
	Baseline	12months
BP \leq 140/85	0.912	0.000
TC \leq 5.0mmol/l	0.346	0.002
BMI \leq 25	0.299	0.025

Results displayed in table 10 show that in each variable there is a statistically significant change between the groups from baseline to 12 months. Of interest BMI is statistically significant ($p=0.025$) for percentages reaching target despite the mean changes between intervention and control being non-statistically significant ($p=0.643$) at 12 months.

6.9 Prophylactic evidence based medication

The same approach was adopted to analyse changes found in prescribing of prophylactic evidence based medication. The findings are displayed below in figures 16-19. As with cholesterol, changes in the guidelines recommended patients with specific criteria (2.6.4) were commenced ACE inhibitors in response to the HOPE study, as such this was implemented and is included in the analysis.

Figure 16 Percentage of patients prescribed Aspirin at 0 and 12 months

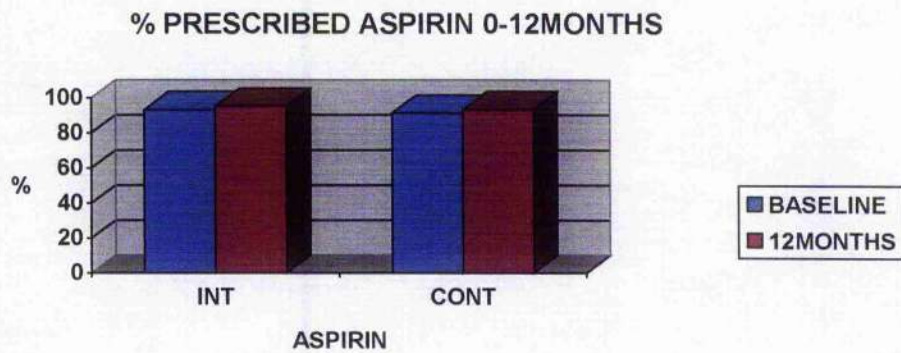


Figure 17 Percentage of patients prescribed Beta Blocker at 0 and 12 months

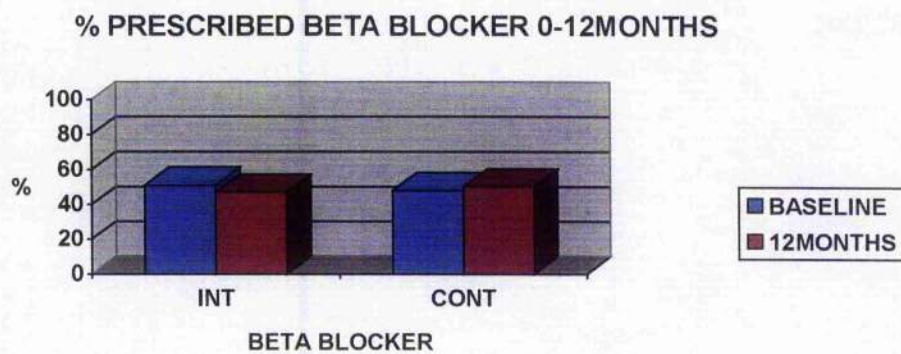


Figure 18 Percentage of patients prescribed Statin at 0 and 12 months

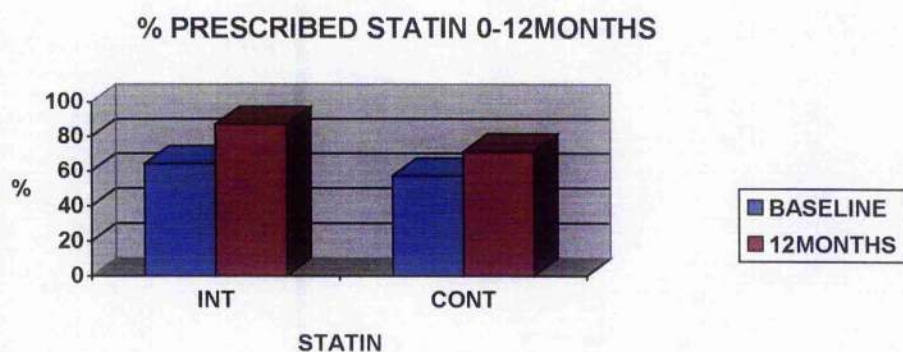
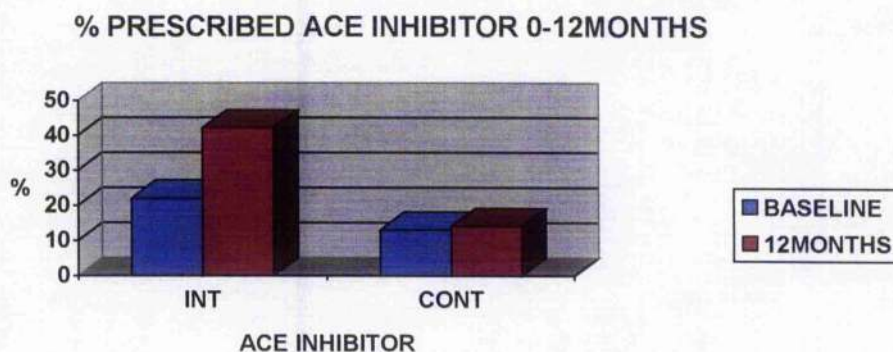


Figure 19 Percentage of patients prescribed Ace Inhibitor at 0 and 12 months



Beta Blocker prescribing was slightly reduced in the intervention group, compared with an increase in the control group. In contrast to this, Aspirin, Statin and Ace inhibitor prescribing improved in the intervention group in comparison to the control group.

Actual numbers are presented for these findings in table 11 below, in addition to, Chi-Square tests at 5% significance level, with 1 degree of freedom, which were undertaken to establish statistical significance.

Table 11 Changes found in prescribing between the two groups at baseline and 12 month follow up

Variable	Baseline			12 month follow up		
	Intervention (n=45)	Control (n=46)		Intervention (n=38)	Control (n=42)	
	n= (%)	n= (%)	<i>p value</i>	n= (%)	n= (%)	<i>p value</i>
Aspirin	42 (93)	42 (91)	0.627	36 (95)	39 (93)	0.729
Beta Blocker	23 (51)	22 (48)	0.754	18 (47)	21 (50)	0.814
Statin	29 (64)	26 (57)	0.597	33 (87)	30 (71)	0.092
ACE Inhibitor	10 (22)	7 (13)	0.391	16 (42)	6 (14)	0.005*

Probability of a difference occurring by chance calculated by using Chi square test at 5% significance level with one degree of freedom

* statistically significant

As an additive to results presented in figs 16–19, table 11 confirms that, Beta Blocker prescribing did indeed increase in the control group, but this was not found to be statistically significant ($p=0.814$).

As previously noted, the prescribing of Aspirin, Statin and Ace inhibitor increased in the intervention group, $p=0.729$, $p=0.092$ and $p=0.005$ respectively, with Ace inhibitor found to be statistically significant.

6.10 Short Form 36 health survey (SF-36)

General health status was examined using the SF36 (Section 3.10.2). Table 12 displays the mean scores for the eight SF-36 domains for both groups at baseline and 12 months.

Table 12 Mean (SD) Short Form 36 health survey (SF-36) scores at baseline and 12 months and mean changes in scores between baseline and 12 months in intervention and control groups

SF-36 domain	Group: <i>Intervention</i> (n=45)	Mean (SD) score		Mean change in score	p value
	<i>Control</i> (n=46)	Baseline	Final		
Physical function	Intervention	68.2(18)	75.3(16)	7.1	0.06
	Control	69.4(24)	71.2(24)	1.8	0.72
Physical role limitation	Intervention	73.3(43)	83.6(34)	10.3	0.23
	Control	66.9(44)	75.6(42)	8.7	0.34
Emotional role limitation	Intervention	85.3(34)	85.0(34)	-0.3	0.97
	Control	80.4(39)	82.5(36)	2.1	0.79
Social functioning	Intervention	85.0(23)	88.6(21)	3.6	0.47
	Control	88.2(21)	82.6(28)	-5.6	0.29
Mental health	Intervention	69.3(24)	73.7(20)	4.4	0.36
	Control	74.6(23)	74.6(22)	0	0.99
Energy and vitality	Intervention	43.1(24)	50.4(20)	7.3	0.13
	Control	46.5(24)	49.0(26)	2.5	0.64
Pain	Intervention	70.2(27)	76.4(21)	6.2	0.24
	Control	76.8(25)	78.0(27)	1.2	0.84
General health perception	Intervention	55.6(20)	61.6(23)	6	0.21
	Control	59.0(24)	62.4(25)	3.4	0.51

The mean scores for the SF-36 domains for both groups do not alter greatly over the 12 months of follow up.

6.11 Alcohol Status

Changes over the year for patient's alcohol consumption were observed in both groups. Patients who reduced their alcohol consumption over the 12 months are presented as 'improved'. A summary of the change in patients units of alcohol a week over the 12 months is illustrated in table 13.

Table 13 Trends in alcohol consumption over the study period - figures are presented in actual numbers

	WORSENERD	NO CHANGE	IMPROVED	TOTAL
INTERVENTION	1	30	7	38
CONTROL	7	30	5	42
TOTAL	8	59	12	79

χ^2 at 5% significance level, with 2 degrees of freedom was performed on alcohol data

Numbers 'improved' in both groups are small, after performing chi-square on the data it can be concluded that there is not a statistically significant difference between the groups, $p=0.389$.

6.12 Analysis by Intention to Treat

Analysis of data so far examines whether the intervention is effective according to the study protocol, rather than focussing on how this may impact the total CHD population being studied. Again, applying two sample t-tests for each variable will allow formal comparisons for intervention and control in terms of mean improvements in risk factors over the 12 months (table 14).

It is important to recognise that in each test, the mean difference of baseline and 12 month value for the control group was subtracted from the mean difference of baseline and 12 month value for the intervention group.

Table 14 Summary of results of two sample t-tests (using analysis by intention to treat)

Variable	Mean difference between 0-12 month		Mean change in score	p value	95%CI for mean diff	Nature of interval
	INT.	CONT.			INT CONT	
SBP	15.18	4.96	10.22	0.017	(1.91, 18.54)	POSITIVE
DBP	11.09	5.80	5.28	0.021	(0.83, 9.74)	POSITIVE
BMI	0.12	0.00	0.12	0.657	(-0.40, 0.63)	Contains Zero
SMOK	1.47	-0.98	2.45	0.004	(0.79, 4.10)	POSITIVE
CHOL	0.62	0.16	0.46	0.025	(0.06, 0.86)	POSITIVE

95% Confidence Intervals for average difference in improvement over the year between the two groups

As demonstrated in table 14, the variables for blood pressure, smoking and total cholesterol all show statistically significant p-values and confidence intervals that do not contain zero. In contrast BMI is non significant and the confidence interval contains zero. From this we can see that it is highly probable that patients in the intervention group experience more of an improvement over the year than the control group.

6.13 Trends in risk factors over 12 months for the intervention group only

Previous analysis confirms that patients in the intervention group show significant improvement in a number of risk factors. In order to examine at what time point patients appear to reach target levels and how long these changes are maintained data were transformed into boxplots (figures 20-23) displaying mean recordings. These boxplots are used to summarise the data at each of the five time points, namely baseline, 3, 6, 9 and 12 months (final).

6.13.1 Blood pressure

Figure 20 Presents the mean recording of systolic blood pressure (SBP) in the intervention group at 3, 6, 9 and 12 months

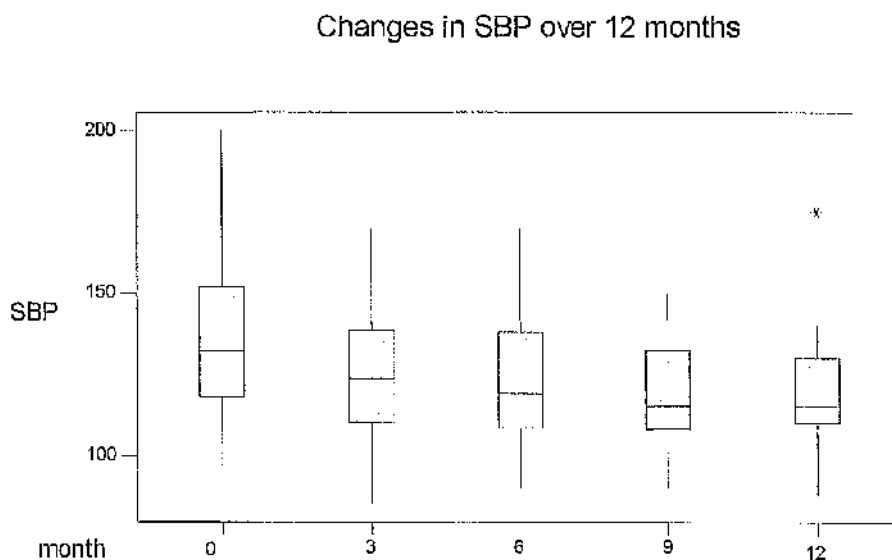
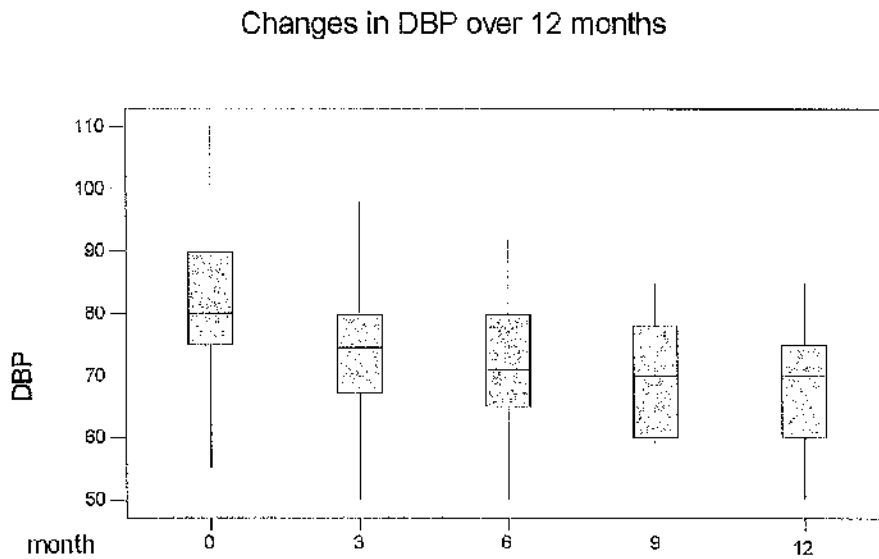


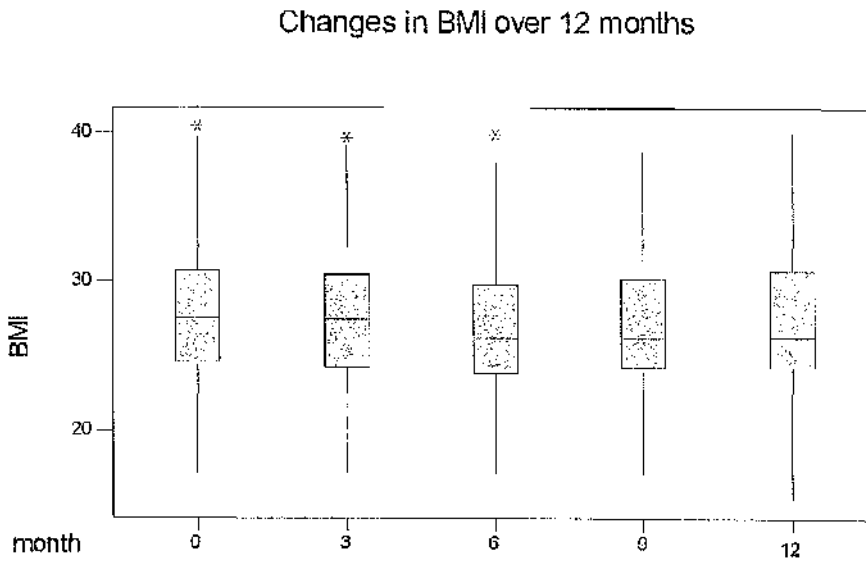
Figure 21 Presents the mean recording of diastolic blood pressure (DBP) in the intervention group at 3, 6, 9 and 12 months



As with systolic blood pressure, the initial descent of the diastolic blood pressure is most noticeable from baseline to 3 months. Again, it is observed that mean diastolic blood pressure remains below target level for the duration of the study.

6.13.2 Body mass index (BMI)

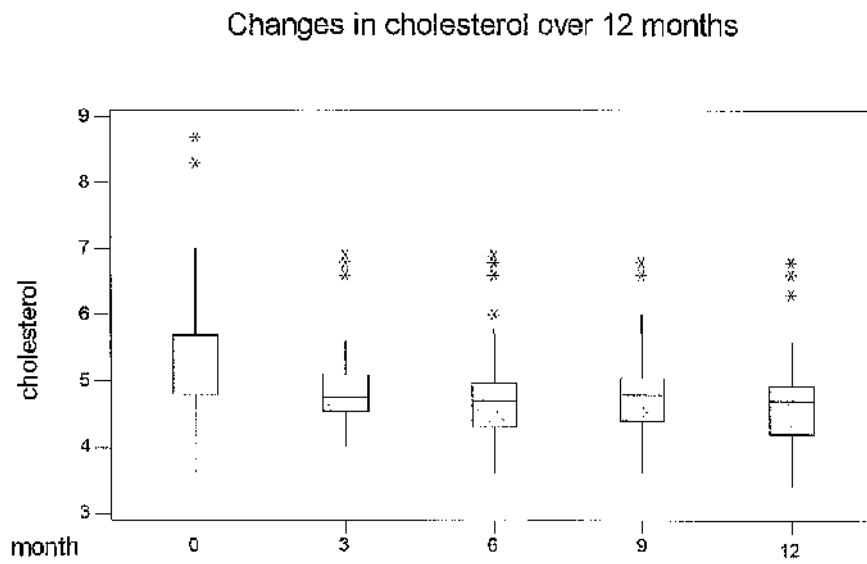
Figure 22 Presents the mean recording of body mass index (BMI) in the intervention group at 3, 6, 9 and 12 months



It can be seen from figure 22 that mean body mass index (BMI) does not alter greatly at any of the protocol time points. There appears to be an initial downward trend in mean BMI, however this is not sustained.

6.13.3 Cholesterol

Figure 23 Presents the mean recording of total cholesterol in the intervention group at 3, 6, 9 and 12 months



Mean total cholesterol values follow a similar pattern to blood pressure, displaying a rapid drop from 0-3 months, with mean total cholesterol remaining below target level for the duration of the project.

6.14 Conclusion

The data produced for phase II, randomised control trial, present an overview of the impact the cardiac nurse specialist (CNS) can make on patients with coronary heart disease (CHD), who are motivated to make healthy lifestyle changes. Implementing the appropriate management of modifiable risk factors and prophylactic evidence based medication. It also gives us an insight into the time frame in which this can be achieved. The following key points summarise the conclusions for phase II.

Phase II

- The CNS significantly improved outcomes in secondary prevention management of motivated patients with CHD.
- This model of care is effective in improving risk factor modification in a group most likely to benefit from such intervention.
- This model of care demonstrates a structured comprehensive care pathway, which could be reproducible

Chapter 7.0 Discussion

7.1 Introduction

To set the scene, the thesis began with a summary of the evidence-base underpinning secondary prevention measures for patients with established coronary heart disease (CHD). A review of the current recommendations for treatment was presented together with literature, which identified deficiencies in the secondary prevention management in patients with CHD. The studies undertaken in this thesis were designed with this background in mind. This chapter presents an overview of the research findings and their contribution to the existing literature. Theoretical and practical implications are discussed and areas of further research are proposed.

7.2 Research Aims and Questions

The aims of this thesis were first to investigate the extent to which secondary prevention measures for CHD patients are managed in a contemporary West of Scotland setting, and second, to evaluate a new healthcare model for the secondary prevention of CHD, with the care to be provided by a cardiac nurse specialist (CNS) working with patients and the healthcare team across the primary and secondary care interface.

7.3 Answering the research questions

This chapter aims to answer the research questions, which were constructed at the outset of the research in order to achieve the aims set out in this thesis. The research questions were:

- What level of coronary risk factor documentation occurs in medical casenotes for those patients with known CHD?
- How effectively are patients with CHD managed in relation to reaching recommended target levels for coronary risk factors?
- What percentage of patients with CHD is prescribed evidence based prophylactic medication?
- What is the general health of patients with CHD as determined by the presence or absence of coronary risk factors?
- What are the perceptions of patients with regard to their current general health?
- How motivated are patients with CHD in making appropriate lifestyle changes?
- How effective is a specialist cardiac nurse (in Primary Care) in improving and managing CHD in those patients motivated to make healthy lifestyle changes?

7.4 Observed levels of coronary risk factor documentation in medical casenotes for those patients with known CHD

Work undertaken by a range of researchers demonstrates a clear reduction in morbidity and mortality from coronary heart disease where appropriate treatment is implemented (Capewell, *et al* 1999). The recommendations as outlined in the Joint British Guidelines (British Cardiac Society 1998) advocate addressing known coronary risk factors, for example blood pressure,

cholesterol and smoking. In addition, they recommend at least annual review of patients with CHD to collect and manage coronary risk factors. Therefore, it was important to establish to what extent evidence based practice was being applied to the management of patients with coronary heart disease locally, and how this compared to work undertaken for other similar surveys examining risk factor documentation in secondary prevention (Aspire Steering Group 1996; Brady, *et al* 2001; Wood *et al* 1997).

Research work for this study was commenced in 1999 and completed early in 2002, and therefore the findings were clinically relevant and comparable to the work undertaken by the researchers above.

The phase I study group consisted of 475 patients of which approximately two thirds were male with an average age of 63yrs and a third were female with an average age of 65yrs. These findings were similar to the age and gender balance present in other demographic surveys of CHD patients (Aspire Steering Group 1996; Brady, *et al* 2001).

A comparison of results in the present study with those presented in ASPIRE was made for blood pressure, smoking, cholesterol and body mass index (BMI). Casenotes were examined for any documentary evidence of these coronary risk factors. Blood pressure and smoking were the most frequently recorded factors for both studies. These findings are consistent with both ASPIRE and Brady *et al* (Brady, *et al* 2001). By contrast to Aspire, an improvement in documentation for cholesterol and weight was observed in the current study (Section 5.4, Figure 3). However, despite 93% of patients having a documented weight in the current study, almost a fifth (19%) had no record of height thereby making it impossible to calculate the BMI or make an assessment of their degree of obesity.

In addition to collecting the above data, data from casenotes were collected to examine if annual recording of risk factors was being undertaken in clinical practice. The results were

disappointing. From an initial review of the results it appeared that coronary risk factors in the current study were well documented, and indeed demonstrated an improvement from the ASPIRE and Brady *et al* data. On closer inspection, the results revealed annual risk factor documentation was not being undertaken (Section 5.4, Fig 3), concurring with other similar studies (EUROASPIRE II Study Group. 2001;Wood *et al* 1997). As few as 40% had annual blood pressure recorded, despite previous findings that blood pressure was the most commonly recorded variable (98%). Similar findings were observed for cholesterol and BMI. This may reinforce the opinion that risk factor screening is often opportunistic. It is perhaps obvious that patients, who are not routinely reviewed, i.e. annually, do not achieve the recommended target levels for coronary risk factors.

7.5 To what extent are patients with CHD managed in relation to reaching recommended target levels for coronary risk factors?

For a number of years the Scottish Executive has identified CHD as an area of high priority with financial incentives being offered to general practice for achieving pre-defined targets regarding risk factor documentation and management. With the introduction of the new GP contract (Department of Health 2003), practices are now not only being rewarded for having coronary risk factors documented but are also required to prove that they have been obtained within a pre-defined time. Further incentives within the contract provide financial rewards for practices achieving target levels, and this will undoubtedly have an impact on future research in this area.

The research for this thesis pre dates the new GP contract (Department of Health 2003) and has demonstrated that implementing evidence based practice and managing patients to target is achievable. During the time course of the work being undertaken for this thesis, the recommendations and target levels changed, for example ACE inhibitor therapy was recommended to certain groups of patients with CHD (Arnold *et al* 2003a), and this is likely to

happen with the GP contract. CHD has clearly been identified as a priority area within the new GP contract and this should be an ongoing process, evolving with the emergence of new research.

The SIGN guidelines (Scottish Intercollegiate Guidelines Network (SIGN) 2002) and the Joint British Guidelines (British Cardiac Society 1998) clearly define the evidence base which has led to the recommended target levels presented in Table 1.

In phase I of the current study, the percentage of patients at target levels for CHD risk factors were compared with findings in ASPIRE (Aspire Steering Group 1996). Like ASPIRE, a substantial percentage of patients did not achieve target levels (Section 5.4, Table 3). For example, in phase I of the study only 43% of patients achieved a target cholesterol level ($< 5.2\text{mmol/l}$). Cholesterol management is relatively straightforward (Brady, *et al* 2001), and statin therapy is better tolerated (Evans 2004).

In phase II (RCT) of this research the mean baseline blood pressure and cholesterol were within target levels (Section 6.5). This does however mask the extent of unmet needs as on further analysis as few as 53% of patients were at the recommended target level of blood pressure $\leq 140/85\text{mmHg}$, and only 40% of patients were at a target cholesterol level of $\leq 5.0\text{mmol/l}$ (this target level had changed during the course of the study). Blood pressure is often difficult to manage and patients often require two or three antihypertensive agents to control their blood pressure (Hansson *et al* 1998).

It is possible that the reason for measuring any of the coronary risk factors is often opportunistic and not systematic, and the consultation will often bear no relationship to CHD. It is likely that any measurement obtained opportunistically is not the priority at that particular consultation. Subsequently, this may not be followed up and acted upon. This being the case, then it may not be surprising that patients do not achieve target levels.

7.6 Prescribing trends for the implementation of evidence based prophylactic medication in patients with CHD

Landmark studies such as 4S (Scandinavian Simvastatin Survival Study Group 1994), ISIS I (First International Study of Infarct Survival Collaborative Group 1986) and HOPE (HOPE study investigators 2000) are examples of large clinical pharmaceutical trials which have contributed to a significant reduction in coronary mortality and coronary event rates. Recommendations for best evidence base treatment emerge from the work undertaken in these studies and are subsequently incorporated into the CHD guidelines (British Cardiac Society, British Hypertension Society, Diabetes, HEART, Primary Care Cardiovascular Society, & Stroke Association. 2005; Scottish Intercollegiate Guidelines Network (SIGN) 2002). The use of Aspirin, or alternative antiplatelet, statins, beta blockers and angiotensin converting enzyme inhibitors (ACE I) are recommended in the secondary prevention management of patients with CHD ((British Cardiac Society, British Hypertension Society, Diabetes, HEART, Primary Care Cardiovascular Society, & Stroke Association. 2005).

To date surveys such as Aspire (Aspire Steering Group 1996), Brady *et al* (Brady *et al* 2001) and Euroaspire II (EUROASPIRE II Study Group. 2001) continue to report sub optimal prescribing of these medications. It is important to recognise that data collected for Aspire were gathered approximately three years prior to this thesis. When results in this thesis for phase I (part A) were compared to Aspire and Brady *et al*, there did not appear to have been any real improvement in the medical management of those patients with CHD. In some areas prescribing trends did in fact appear worse. For example, in phase I of this thesis Aspirin was prescribed in 76% of all patients with known CHD, versus 86% in Aspire. The research undertaken in phase I (part B) indicated that where some patients may have bought their aspirin over the counter (OTC), this was still being recorded on the practice database as being prescribed, which is important when undertaking audit. Although we cannot assume the patients not prescribed Aspirin were buying this OTC, from the results it would suggest that this is not the case.

By contrast, statin prescribing was improved in this research with 56% of CHD patients being prescribed statin compared to only 16% in Aspire and 18-20% in Brady *et al.* This increase may be contributed to the dissemination of CHD guidelines such as SIGN (Scottish Intercollegiate Guidelines Network (SIGN) 2001) and the Joint British Societies Guidelines (British Cardiac Society, British Hypertension Society, Diabetes, HEART, Primary Care Cardiovascular Society, & Stroke Association. 2005). Statins are well tolerated with good safety and efficacy profiles (Evans M 2004). This increase is encouraging however perhaps more work needs to be focused on patients being prescribed not only the appropriate medication but also at an appropriate dose as less than half the patients were found to be at the recommended target level (Section 5.4, Table 3). Similar trends were observed for beta blocker and ACE I therapy. These results concur with other surveys of this nature and may support a different approach to CHD management.

7.7 Sub optimal management does not appear to affect patients perceptions of general health

Risk scores for patients with CHD are routinely used in clinical practice (TIMI study group 2006). Prior to undertaking the casenote review for phase I (part A) of the thesis, the CNS compiled risk groups in an attempt to categorise patients into low (low risk factor profile) to high (high risk factor profile) risk groups (Section 6.3, table 4). This was undertaken to identify whether patients found to be in a higher risk factor category were less likely to respond to the postal questionnaire and randomised control trial (RCT). Another aspect of the research undertaken in phase I (part B) of this thesis was to examine patients perceptions of general health (Section 4.14.1). Patients answering these questions were more likely to indicate their health was average or above. In phase II (RCT) the short form 36 (SF36) (Ware & Sherbourne 1992) was used to measure quality of life. Mean baseline scores in both groups were found to be similar to that of normative data from a large community sample (Jenkinson, *et al* 1993) (Section 6.10, table 11). This data

gathered for phase I and II of this thesis may imply that the cohort of patients being studied were generally reporting good health. No statistically significant change in SF36 scores was observed in either group at 12 months following the RCT.

7.8 Patient motivation to make healthy lifestyle changes

It has been cited in this thesis, that perhaps one of the biggest barriers to achieving risk factor targets and making appropriate lifestyle changes, is patient motivation. Patient compliance to particular interventions are often very much dependent on their own health beliefs, perceptions and understanding of the particular condition or topic.

In phase I (part B) of this thesis the postal questionnaire achieved a 76% rate. This may indicate that this was a motivated group of patients who responded. It is possible that this could be a reflection of the postal questionnaire and supporting letter being well constructed (Appendix VII and IV) making it easier for patients to understand and respond to (Walonick 2005). This supporting letter informed the patient of the purpose and rationale of the study in addition to highlighting that by responding they might be asked to contribute further with the research in participation with the RCT. This may also support the health belief model demonstrating that when patients understand what is being investigated they are more motivated to comply (Hiatt, ,Schechtman).

Patients responding to the postal questionnaire in phase I (part B) were asked to indicate their motivation to make healthy lifestyle changes. Of those responding 66% indicated they felt they could improve aspects of their lifestyle, with a further 9.5% stating they had 'never thought about it' (Section 5.10, figure 6).

The research for phase II (RCT) of this thesis was targeted only at those patients indicating a response to make changes or as above, who had 'never thought about it'. The patients who indicated they were 'not interested' were not contacted further. This could perhaps be considered as a study limitation and will be discussed further later in this chapter.

What was interesting about the questionnaire responses was the reason patients were motivated to make healthy lifestyle changes (Section 5.11, figure 8), almost all of the respondents indicated health and fitness as the key reason. In phase II (RCT), there was an observed dip in body mass index (BMI) in the summer months, this could perhaps suggest that patients were attempting weight loss prior to a summer holiday, or that patients feel better in the summer months due to the longer days and weather.

7.9 The impact of the CNS in improving and managing CHD in those patients motivated to make healthy lifestyle changes

The National Service Framework (NSF) (Department of Health, 2000) states that prior to leaving hospital, all patients with heart disease should be invited to participate in a multidisciplinary programme of cardiac rehabilitation which includes implementation of secondary prevention measures. Patients participating in the research project presented in this thesis would probably be suitable for phase 3 or 4 of the new SIGN guidelines for cardiac rehabilitation (Scottish Intercollegiate Guidelines Network 2002), however the research pre dates this. Nevertheless, cardiac rehabilitation guidelines have been established for a number of years, but often as recommended above, they are targeted at patients on discharge from hospital. The majority of patients participating in this research study may never have had a hospital admission.

SIGN 57 (Cardiac Rehabilitation) guidelines (Scottish Intercollegiate Guidelines Network 2002) emphasise the importance of managing secondary prevention of CHD in the community, with input from the primary care team. In order to facilitate this, incentives such as the General Practice Exercise Referral Scheme (GPERS) and GRASSP were piloted. These programmes promoted management of coronary risk factors within the community. Work for both of the above was in it's infancy at the time of the work being undertaken for the research presented in this thesis. Following consultation with the Public Health department within the Greater Glasgow National Health Service Board (GGNHSB), it was agreed that intervention patients participating in the research for this thesis could access the GPERS. Evaluation of this programme was not available on completion of the research, however anecdotal evidence suggested that this was a very positive service for patients with CHD.

Since the completion of this thesis other similar programmes promoting health have been established within GGNHSB, for example, the "Hearty Eating Programme" and the introduction of smoking cessation programmes. Secondary care may be unaware of the services available to patients with CHD in their community. The implementation of a CNS integrating care between primary and secondary care may help to facilitate appropriate referrals to these programmes, reinforcing positive health promotion.

Clinical guidelines for the management of CHD (British Cardiac Society, British Hypertension Society, Diabetes, HEART, Primary Care Cardiovascular Society, & Stroke Association. 2005;Scottish Intercollegiate Guidelines Network (SIGN) 2001) are widely accessible in both primary and secondary care yet as described earlier in this chapter, patients continue to receive sub optimal management.

Different approaches to the promotion of secondary prevention of CHD have been evaluated (Campbell *et al* 1998a;Jolly *et al*1999) with varying degrees of success. Work undertaken by Campbell *et al*, in the Grampian region of Scotland, and Jolly *et al* , in Southampton in England

(the SHIP study), was compared with the findings of phase II (RCT) of this thesis. To summarise, a different model of care was delivered in all three studies. No significant improvements were made in the CHD management of patients studied in the SHIP (Jolly *et al* 1999) study, however the study was felt to be successful from a methodological viewpoint.

Patients in the intervention group in Grampion region (Campbell *et al* 1998a) were seen once at baseline and then encouraged to attend for follow up anything from 2 to 6 monthly. In the current study (phase II (RCT)), a structured approach was used and fixed 3 monthly reviews were made with patients recruited to the intervention group. Patients in the SHIP (Jolly *et al* 1999) study were not seen by the CNS, follow up was by self-administered questionnaire. The nurse specialists worked as a liaison service, this model may have improved communication however did not have any impact on patient care.

Within the intervention group of the current study 79% of patients reached a target cholesterol level of $\leq 5.0\text{mmol/l}$ compared to 41% with a target level of $\leq 5.2\text{mmol/l}$ in the intervention group in Grampion (Campbell *et al* 1998a). Both the current study and Grampion study (Campbell *et al* 1998a) achieved improvement in the percentage of patients achieving target blood pressure, however the target level in the current study was lower, 97% (140/85mmHg), versus, 96.5% (160/90mmHg) in the Grampion study (Campbell *et al* 1998a). The target levels for cholesterol and blood pressure outcomes were lower in the current study, this may be a reflection of the time in which Campbells work was undertaken.

The most striking observation when all three studies were analysed was the difference in smoking habits in the current study compared to the others. Neither the Grampion study (Campbell *et al* 1998a) or SHIP (Jolly *et al* 1999) were able to impact on smoking (Grampion, smokers at baseline $n= 482$, 12 months $n= 482$), (SHIP, smokers at baseline 19%, 12 months 20%). In the current work, 21 % of patients studied in phase II (RCT) were smokers at baseline, at 12 months 40% of patients in the intervention group ceased to smoke, with a further statistically significant reduction

in the number of cigarettes smoked ($p=0.004$). Observed baseline figures for smoking in Grampion (19%) were slightly lower than that found in SHIP and the current study (21)% in phase II (RCT). This could suggest that this group of smokers were long-term smokers who may not see smoking as a priority area to address.

In addition to the above, prescribing trends were compared with the work undertaken by SHIP (Jolly *et al* 1999) and in Grampion (Campbell *et al* 1998a). The SHIP study (Jolly *et al* 1999) did not examine prescribing trends. Patients within the intervention group in Grampion group (Campbell *et al* 1998a) achieved improvements in Aspirin prescribing 69.4% - 81%. Within the current study, Aspirin prescribing in patients at baseline for both groups was in fact excellent were (93% intervention, versus 91% control). Patients within both group groups achieved further non significant improvement in Aspirin prescribing.

As described previously, statin therapy is relatively straightforward (Brady, *et al* 2001) and statins on the whole are well tolerated (Evans 2004). Patients recruited to the intervention group achieved better cholesterol management, compared with the control group. Cholesterol levels were obtained from patients in both groups at baseline, yet the intervention group achieved better results in prescribing of statins and also in the percentage of patients reaching target cholesterol level. Both patients and their GPs in the control group were told their baseline cholesterol level and advised by the CNS to address this. The reasons why patients in the control group did not achieve better results is outwith the scope of this study. It is possible that patients were commenced statin therapy or existing therapy was increased following the baseline reading. There is evidence to suggest that as many as 50% of patients will have stopped taking their medication at one month. Patients in both groups at baseline were felt to be motivated and perhaps more likely to make appropriate changes. It is therefore difficult to understand why patients in the control group may not have been motivated to make the recommended changes. The differences observed between the control and intervention groups in the current study may support the model of care evaluated in the RCT.

The evidence in the literature reports patients are receiving sub optimal care (Brady *et al* 2001) and perhaps the existing models of care need to be re-evaluated. It may be that the majority of patients with CHD receive usual care from their health care team in both primary and secondary care, but is this enough?

Other models of care may exist however as yet there is little evidence to suggest secondary prevention management is improving. The new model of care evaluated in phase II of this study was successful, possible explanations for this include; appropriate time allocated to appointments to incorporate appropriate education and support; regular follow up at clinics reinforcing the same key health messages, which may then be recognised by the patients as important areas of their health to consider; using motivational interviewing techniques to move patients from one stage of change to the next; and delivering a model of care using a structured comprehensive approach therefore ensuring all the relevant areas are covered.

Moreover, with the advent of the new GP contract (Department of Health 2003) there is perhaps scope for this role to be undertaken at a Nurse Consultant level. Implementation of Nurse Consultant clinics for chest pain (Pottle 2005) and atrial fibrillation (Tagny 2005) have demonstrated success. Using the model in this thesis a Nurse Consultant could help to facilitate the aims and objectives set out in the GP contract.

Finally, using an integrated approach offering the patients 'specialised' care delivered by the CNS may improve outcomes. This model of care may provide improved outcomes for patients with CHD.

7.10 Study limitations

- In phase I (part A) of the research, a retrospective casenote analysis was undertaken to collect data to examine the extent to which secondary prevention treatment is achieved in patients with CHD. Although the CNS made every effort to collect all the relevant data it cannot be assumed that data not found to be recorded in the casenotes had not previously been obtained. It is possible that information is collected and recorded in a different format.
- In phase I (part B) of this research, the postal questionnaire sent to patients with CHD asked patients to indicate their motivation to make healthy lifestyle changes. For those patients who responded indicating they were 'not interested', the CNS made no further contact. This model set out to examine whether the model of care being evaluated could be effective in patients motivated to make healthy lifestyle changes. As described in section 7.11 further research in the group of patients apparently poorly motivated would be valuable.
- In phase II (RCT) a sole researcher, namely the CNS, undertook the study. To reduce any personal bias the CNS had to ensure that the research methods were robust. For this reason the CNS was not involved in the randomisation process, this was undertaken using computerised random number tables, and was executed by a member of the hospital research and development team. Also, randomisation of the patients was undertaken after the baseline visit to further reduce personal bias.

7.11 Recommendation for further research

The research conducted for this thesis has emphasised that the management of patients with CHD is sub optimal but can be significantly improved with a comprehensive and structured approach using CNS-led clinics. The CNS is ideally suited to delivering this model of care however the research in this thesis has highlighted further questions, which at present are unanswered. Further research should: explore whether the same model of care delivered by the CNS can be replicated in all GP practices and identify what the potential barriers to delivering this model of care may be. This could be undertaken by means of a RCT of CNS intervention compared to usual care in a wider group of GP practices, for example a Local Health Care Co-operative (LHCC). Practices would ideally be stratified for socio-economic status. Future research could also explore whether other health professionals could deliver this model of care, namely the practice nurse and general practitioner, achieving improved secondary prevention management for patients with CHD. The question of choosing only motivated patients could be examined. It would be of interest to attempt to intervene on the group of patients who appeared not to be motivated to make healthy lifestyle changes.

It had been anticipated by the CNS that a cost analysis of the model of care delivered in this thesis would be undertaken. Unfortunately due to other commitments the advisor involved was not able to fulfil this request. In the current environment where financial implications are a major consideration this would be an area where further research may strengthen the argument for the CNS.

Obesity (section 2.4.5) and inactivity (2.4.6) are recognised risk factors contributing to CHD. Although patients were asked about their exercise capacity no formal validated instrument was used to evaluate this. With the introduction of the Physical Activity Strategy (ref), it is hoped that by 2021 50% of the Scottish population will be achieving 30minutes of moderate activity on most

days. Exercise is known to be of benefit to patients with CHD and further research specifically measuring exercise habits would be of interest.

Finally, as clinically significant changes in cardiac event rates are not expected within the time frame of the research for the thesis, it would be interesting to follow up this cohort of patients 5 years from the initial contact to examine further outcome measures. The ultimate goal is for survival and a reduction of cardiac event rates.

7.12 General conclusions

Sub-optimal risk factor documentation and management of patients with CHD continues to exist in current practice. The CNS model of care significantly improved outcomes in the secondary prevention management of patients with CHD motivated to make lifestyle changes. Improvements were observed in smoking, cholesterol, and blood pressure. Improvements although not significant were made in weight management. Prescribing trends in prophylactic medication were also improved for the majority of medications which are recommended for the secondary prevention of patients with CHD. Further research may wish to examine whether this model of care can be effective in patient groups considered to be poorly motivated with higher levels of risk factors present. This thesis has demonstrated that a model of care, based in primary care, delivered by a CNS in partnership with the GP practice team is effective in improving risk factor modification in a group most likely to benefit from such intervention.

7.13 Full Circle

This research began with the identification of sub optimal treatment for the secondary prevention management of patients with CHD. Different models of care have previously been examined but the research in this thesis aimed to test the impact of a new model of care in primary care, delivered by a CNS from secondary care. The results from this thesis have demonstrated that this model of care is effective in improving risk factor modification in a group most likely to benefit from such intervention. In addition to this, the new model of care demonstrated a structured comprehensive care pathway, which could be reproducible.

On completion of the work undertaken for this thesis, a secondary prevention project was proposed within the Local Health Care Co-operative, (LHCC) where the CNS was working. In line with best practice, and in response to national and local health priorities, Priority Projects were being established. These projects were in many ways pilot studies in anticipation of a chronic disease management (CDM) programme which has now been established by the Greater Glasgow National Health Service Board (GGNHSB). Practices involved in the Priority Projects chose an area of health felt to be of particular relevance to their practice populations needs.

Strathkelvin LHCC, in the North of Glasgow, chose “Secondary Prevention of heart attacks and stroke” as the focus for their “Priority Project”. The project aimed to provide optimal care in accordance with current evidence-based guidelines and reduce morbidity and mortality from CHD and CVD.

As a result of the outcomes achieved in the research presented in this thesis, the CNS was invited to project manage the Priority Project. The model of care used in this thesis was replicated in all patients with coronary heart disease and cerebrovascular disease. One of the main barriers to

delivering the care to patients was in fact a shortage of nurses. In many practices the Practice Nurses were unable to take on the extra commitment of the secondary prevention clinics. The concept of integrating nurses from secondary care to primary care was proposed to the practices. Practices were aware that the integrated model of care had previously worked with the randomised control trial in this thesis, so were receptive to the idea. In six of the twelve practices a cardiac nurse specialist (CNS) from secondary care undertook the secondary prevention clinics. Nurses integrated well, and although the project has now concluded, some of the nurses continue to undertake clinics on a weekly basis. This hopefully demonstrates this new model of care, delivering a structured comprehensive care pathway, can be reproducible.

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**Appendix I: Coronary event rates per country from the WHO MONICA Project for
(a) men and (b) women**

Coronary event rates per country from the WHO MONICA Project for (a) men and (b) women

Fig 2.2a Age-standardised coronary event rates, men aged 35-64, latest available data, MONICA Project populations

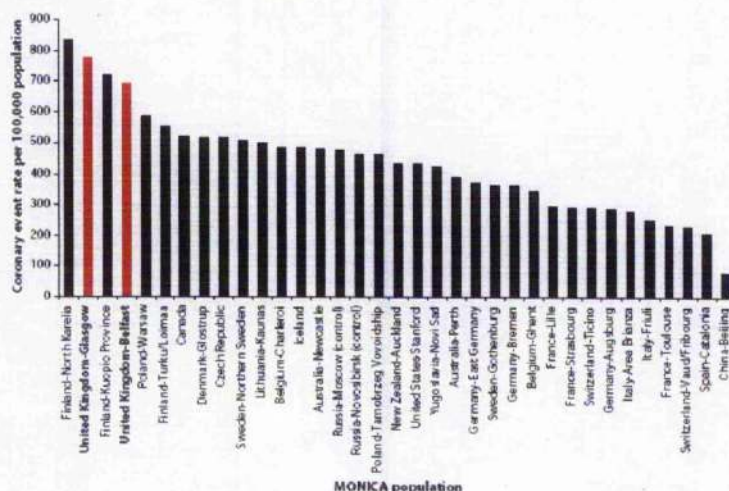
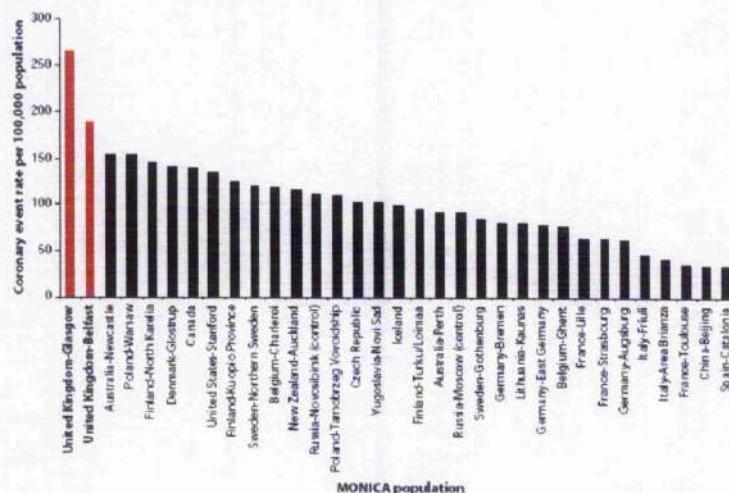


Fig 2.2b Age-standardised coronary event rates, women aged 34-65, latest available data, MONICA Project populations



British Heart
Foundation
Statistics Database
www.heartstats.org

Source: British Heart Foundation Statistic Database, www.heartstat.org

Appendix II: ABCD to hypertension

ABCD Treatment algorithm for hypertension

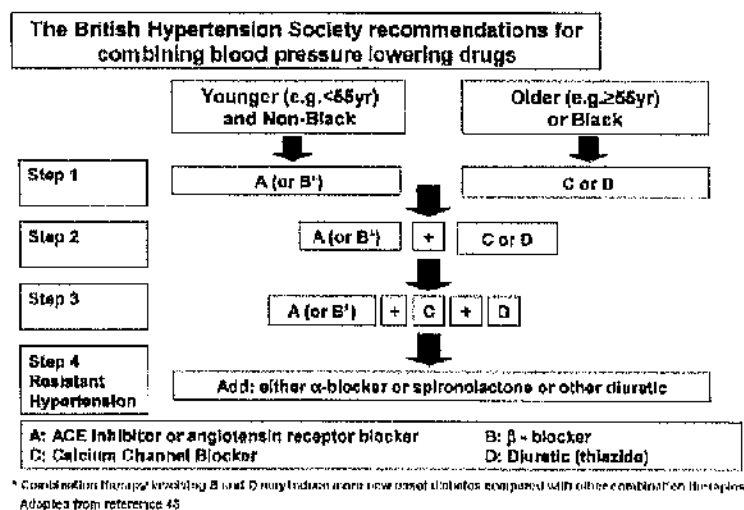


Figure 3 Recommendations for combining blood pressure lowering drugs/ABCD rule.⁴⁵

Source: Williams et al 2004

Appendix III: Body Mass Index Calculation

Body Mass Index Calculation

Body Mass Index (BMI)

To take account of the expected differences in weights in adults of different heights, a simple index of weight-for-height has been devised as the body mass index (BMI). This is calculated as:

$$\text{BMI} = \frac{\text{Weight kg}}{\text{Height m}^2}$$

An adult of 70 kg with a height of 175 cm has a BMI of:

$$\frac{70}{1.75^2} = 22.9$$

The internationally accepted ranges⁽¹¹⁾ of BMIs are as follows:

Underweight:	<18.5
Normal:	18.5-24.9
Overweight:	25.0-29.9
Obesity:	30.0-39.9
Extreme obesity:	≥40

A BMI <17.5 has been taken as one criterion of anorexia nervosa⁽¹²⁾.

Source: Scottish Collegiate Guidelines Network(www.sign.ac.uk)

Appendix IV: Proposal for Ethical Approval

Proposal submitted to Local Research Ethics Committee

1. RESPONSIBLE INVESTIGATORS

Katy Joss
Frank Dunn

2. TITLE OF PROJECT

Coronary Heart Disease Integrated Care Project
Stobhill NHS Trust with General Practitioners – North Glasgow

3. SUMMARY OF AIM AND BACKGROUND

Coronary Heart Disease (CHD) remains the major cause of morbidity and mortality in the Western World with event rate and mortality being particularly high in the West of Scotland in both men and women. Concern remains about the implementation of the evidence based practices in patients with coronary artery disease. In addition more effective methods of health promotion and education are required. The concept of specially trained nurses in providing the link between primary and secondary care is being explored in a number of areas and this may be one way to integrate care for patients with coronary artery disease.

A number of articles have recently appeared in the medical literature to suggest that the concept of managed care performed by specially trained nurses could be a step in the right direction for patients. If positive results are obtained, designated nurses could have a major role to play in risk factor screening and management for patients with coronary artery disease. This also may lead to a major beneficial effect on our overall delivery of health care and costs.

4. SUMMARY OF METHODOLOGY

We would aim to visit three Medical Practices in the North of Glasgow. With consent from the General Practitioners we wish to obtain information from their database (a template will be compiled to identify patients with established or suspected coronary artery disease). Once we have identified the patients suitable for the study we will then, with the patients consent, obtain information on their current medical treatment and investigate their risk factors for CHD.

The following variables will be assessed:

- Physical wellbeing
- Incidences of chest pain
- Smoking
- Blood Pressure
- Lipid analysis
- Weight
- Exercise
- GP appointments and outpatient appointments
- Hospital admissions with suspected cardiac problem

Postal Questionnaires have been designed for patients to complete. Patients responding to questionnaire will be randomly allocated into two groups for either control or intervention. Having evaluated all the information on the intervention group, a managed care programme will be structured for individual patients covering their specific needs. The patients will then be closely monitored with respect to the above points at three monthly intervals for twelve months. Patients in the control group will be assessed once, given appropriate health education and health promotion leaflets and a further final assessment will take place at twelve months.

5. ANTICIPATED DURATION OF THE PROJECT

2 years

6. DRUGS TO BE ADMINISTERED FOR EXPERIMENTAL PURPOSES

None

7. NON-STANDARD PRODUCTS TO BE ADMINISTERED FOR EXPERIMENTAL PURPOSES

None

8. THE USE OF RADIOACTIVE MATERIALS

None

9. CERTIFICATE OF INDEMNITY

Not Applicable

10. If the project is grant aided confirmation that the source of the grant accepts liability must be provided

Not Applicable

11. APPROPRIATE CLINICAL TRIALS CERTIFICATE/EXEMPTION FORM

Not Applicable

12. CONFIRMATION OF CURRENT MEMBERSHIP OF A MEDICAL DEFENCE UNION

Dr Frank Dunn	YES
Ms Katy Joss	Not Applicable

13. PERSONAL EXPERIENCE

Dr F G Dunn has undertaken considerable research in the field of coronary heart disease

Katy Joss is a cardiology sister with extensive clinical experience in the management of coronary heart disease.

14. PATIENT CONSENT AND INFORMATION FORM

See enclosed

15. FINANCIAL IMPLICATIONS

Nil

16. DECLARATION

Enclosed

14. Patient Information

~ Below contact letter for Questionnaire

Dear

We have been approached by the Cardiology Department at Stobhill Hospital and asked to work with them on a project which aims to identify and reduce risk factors for individual patients with a known or suspected history of Coronary heart disease.

These risk factors, which include blood pressure, cholesterol, smoking, alcohol, diet, exercise and stress are probably known to you through discussions with ourselves or the hospital, but this project plans to go one step further.

In this respect, the Cardiology Department has seconded a nurse with specialist Cardiology training, Katy Joss, to work with the Practice on this new initiative.

As someone who has been selected as suitable for inclusion, we would ask you to fill in this simple questionnaire. It should take about 15 minutes to complete.

You may also be contacted with regard to attending a short interview at the Practice. This interview will be part of the fuller project and Katy will telephone you personally to discuss this.

There is, of course, no pressure on you to do this, but we hope you will feel able to take part. If you agree to take part in the study it may be of little benefit to you personally. However, the results may help other patients in the future. Should you not wish to take part this will not affect your usual treatment in any way. Information collected will remain confidential.

If you have any queries, please contact us at the Surgery.

Thank you

Yours sincerely

14. **Patient Information continued..**

~ Below contact letter for interview/assessment

Dear

I would like to thank you for taking the time to complete the recent questionnaire regarding your heart and health, which Katy and I have now had a chance to review.

In the light of your answers, we feel it would be appropriate for you to come into the Practice for the interview we mentioned. Patients being invited to attend for interview will be randomly selected into two groups.

Group one - patients in this group will be assessed and followed up by Katy every three months for one year.

Group two - patients in this group will be assessed and given relevant health promotion and health education. They will then be assessed again by Katy at one year.

The assessment will take approximately one hour and will involve the following:

Looking together at your risk factors for heart disease

Obtaining an up-to-date record of your blood pressure, weight, diet, cholesterol, smoking history, etc

Discussing any questions you may have regarding your heart/health

To arrange this interview, Katy will contact you by telephone and invite you into the Practice at a time suitable to you both. As before, we hope you will want to take part in the study, but you are under no obligation to do so.

Please feel free to contact me at the Practice should you have any questions.

Yours sincerely

CONSENT FORM

Coronary Heart Disease Integrated Care Project Stobhill NHS Trust with General Practitioners – North Glasgow

Iof

have had the opportunity to discuss the study with Katy Joss and understand that participation in this research is voluntary and I can withdraw at any time without it affecting my treatment.

I hereby consent to the participation in the above study.

Signed Date

PRINT NAME (Patient)

Signed Date

PRINT NAME (Research Nurse)

Appendix V: Proforma

**CHD Integrated Care Project
Stobhill NBS Trust with General Practitioners - North Glasgow**

PROFORMA FROM PATIENTS CASENOTES

GP Practice: CHI no. GP:

Patient name: Date of Birth:

Address: Sex:

.....

.....

Postcode:

PAST MEDICAL HISTORY

Cardiac Non cardiac Not recorded ☐

FAMILY HISTORY OF HEART DISEASE: Yes ☐ No ☐ Not recorded ☐

CURRENT MEDICATION

Medication	Dose	Frequency	Date of most recent rec.

Who did patient first present to with possible cardiac symptoms:

Hospital ☐ GP ☐

What year did they first present:.....

REFERRALS

Cardiology Clinic Yes ☐ No ☐
No. of times attended =

Fast track Yes ☐ No ☐

Exercise testing Yes ☐ No ☐
No. of times exercised =

Echo Yes ☐ No ☐
No. of echos carried out =

Cardiac Rehab Yes ☐ No ☐

Angiography Yes ☐ No ☐
No. of Angios carried out =

Angioplasty Yes ☐ No ☐
No. of times angioplasty carried out =

CABG Yes ☐ No ☐
No. of CABGs =

Thallium Yes ☐ No ☐

GENERAL STATUS OF PATIENT AT PRESENT

Recording	Date last recorded	Recording	Action required	Rec in last year Yes <input type="checkbox"/> No <input type="checkbox"/>
Blood Pressure				Yes <input type="checkbox"/> No <input type="checkbox"/>
Cholesterol				Yes <input type="checkbox"/> No <input type="checkbox"/>
Weight				Yes <input type="checkbox"/> No <input type="checkbox"/>
Smoking				Yes <input type="checkbox"/> No <input type="checkbox"/>
Bloods				Yes <input type="checkbox"/> No <input type="checkbox"/>
Medication				Yes <input type="checkbox"/> No <input type="checkbox"/>

Patients Height (in cm) Not recorded ☐

BMI – Not recorded ☐

Identified Risk Factors

Hypertension	Cholesterol	Smoking	Obesity	Diabetes

Attends Cardiovascular Clinic ☐

Attends Hypertension Clinic ☐

Attends Diabetic Clinic ☐

No. of times patient has attended GP in the last year =

No. of hospital admissions with possible cardiac symptoms in the last year =

ACTION PLAN -

Would like to send out questionnaire Yes ☐ No ☐

GROUP:

If No, state reason

Appendix VI: GP consent forms for contacting patient by postal questionnaire

Appendix VII: Postal questionnaire

**Coronary Heart Disease Integrated Care Project
Stobhill NHS Trust with General Practitioners-North Glasgow**

Please complete the following questionnaire which will be treated in strictest confidence. A space for additional comments has been left at the end. Please feel free to add any comments you feel are relevant.

Thank you for taking the time to complete this questionnaire.

Name: Date of Birth:

Address: Sex:

.....

..... Postcode

Living arrangements

Live alone: ☐ Live with partner: ☐

Live with your young children: ☐ Live with your son/daughter and family: ☐

Live in sheltered housing: ☐ Live in a nursing home: ☐

How many people are there in your household

1 If you have ever had chest pain, when did you first see your GP about it?

Within the last 3 months ☐ Within the last 6 months ☐ Within last year ☐

Over one year ago ☐ 2-5years ago ☐ 5-8years ago ☐

8-10 years ago ☐ >10years ago ☐ Not relevant ☐

2 If you get chest pain how often does it occur?

- Every day ☐ 2-3 times a week ☐ Once a week ☐
☐
 2-3 times a month ☐ Once a month ☐ Very rarely ☐
 Never ☐

3 How often do you use your nitrate spray or nitrate tablet under tongue?

- Every day ☐ 2-3 times a week ☐ Once a week ☐
☐
 2-3 times a month ☐ Once a month ☐ Very rarely ☐
 Never ☐

4 If you never use a nitrate spray or tablet is this because:

- You never have pain ☐ You have pain, but you can't use it ☐
 You have pain but you don't have a nitrate spray or tablet ☐

5 Do you have any family history of Angina or Heart Attack? ☐ Yes ☐ No

6 That you are aware of, which of the following family members have had Angina/Heart Attack?

Father		Mother	
Brother		Sister	
Aunt		Uncle	
Son		Daughter	

7 Have you ever had a heart attack?

☐ Yes ☐ No ☐ Don't know

Do you have high Blood Pressure?

☐ Yes ☐ No ☐ Don't know

Do you have diabetes?

☐ Yes ☐ No ☐ Don't know

Do you Smoke?

☐ Yes ☐ No

Have you ever had your cholesterol checked?

☐ Yes ☐ No ☐ Don't know

Do you know what your cholesterol level is?

☐ Yes ☐ No

If Yes, what is your cholesterol level reading

.....

8 What is your weekly alcohol consumption? Please list the number of drinks you would be likely to have on an average week. For example, you could list what you had last week:

Day of Week	Number of drinks	Type of drink
eg Monday	Three pints	Beer
Monday		
Tuesday		
Wednesday		
Thursday		
Friday		
Saturday		
Sunday		

About your medication

9 Are you taking any medication at the moment? ☐ Yes ☐ No

10 If Yes, please list below:

Medication	Dose	What times of day

11 Do you ever miss taking your medication? ☐ Yes ☐ No

12 Do you find it difficult taking your medication? ☐ Yes ☐ No

13 In the last year have you been admitted to hospital with your heart condition?

☐ Yes ☐ No

14 If Yes, how many times in the last year have you been admitted:

Once ☐ Twice ☐ Three times ☐ Four times ☐

Five times ☐ Five to ten times ☐ More than ten times ☐

About your General Health

15 How would you rate your general health?

Very Good	<input type="checkbox"/>	Good	<input type="checkbox"/>
Average	<input type="checkbox"/>	Poor	<input type="checkbox"/>
Very Poor	<input type="checkbox"/>		

16 How would you rate your general fitness?

Very Good	<input type="checkbox"/>	Good	<input type="checkbox"/>
Average	<input type="checkbox"/>	Poor	<input type="checkbox"/>
Very Poor	<input type="checkbox"/>		

17 How would you rate your diet?

Very Good	<input type="checkbox"/>	Good	<input type="checkbox"/>
Average	<input type="checkbox"/>	Poor	<input type="checkbox"/>
Very Poor	<input type="checkbox"/>		

18 Do you feel you could improve aspects of your lifestyle? ☐ Yes-go to question 19

☐ No-go to question 21

19 If Yes, what aspects could you change?

Smoking ☐
Diet ☐
Exercise ☐
Alcohol ☐

20 Why do you feel you want to change these aspects?

Health ☐
Fitness ☐
Money ☐
Self confidence ☐
Challenge ☐

21 If No, is this because?

Your lifestyle is healthy ☐
You are not interested ☐
You have never thought about it ☐

22 What encourages you to make changes in your lifestyle?

Family support ☐ Want to feel fitter ☐
Medical reasons ☐ Going on holiday! ☐
Want to save money ☐ Personal reasons ☐

Any other reasons

23 In the past have you been given any education about healthy living or heart disease?

☐ Yes ☐ No

24 If Yes, then where did you get your advice? Tick as many as applicable.

General Practitioner	
Hospital Doctor	
Practice Nurse	
Cardiac Rehab (Hosp)	
Books and Magazines	
Other (please state)	

Thank you again for taking the time to fill in this questionnaire.

Please use the space below to add any additional comments you feel are relevant.

Please return the completed questionnaire in the envelope provided to:

Katy Joss
 Peel View Medical Practice
 45-53 Union Street
 KIRKINTILLOCH
 GLASGOW
 G66 1DL

Appendix VIII: Interview Schedule

**Coronary Heart Disease Integrated Care Project
Stobhill NHS Trust with General Practitioners-North Glasgow**

FIRST ASSESSMENT RECORD

Patient Details : Today's Date :

.....

abcdefghijklmnopqrstuvwxyz

Past Medical History :

▲ 2015年10月1日起，凡在《中国好声音》总决赛中夺冠的歌手，其作品将自动获得2016年央视春晚演唱资格。

x x x : d + u k l m n o p r + h + i j k l m n o p q r s t u v w x y z

Current Medication taken by patient :

[illegible]

Observation	Recording	Date next due	Signed
BP on arrival			
BP after 5 mins			
Weight in KG			
Height in cm			
If Smoker - amount			
Cholesterol			
If no chol then obtain			
Todays date			

Observation	Recording	Date next due	Signed
BP on arrival			
BP after 5 mins			
Weight in KG			
Height in cm			
If Smoker - amount			
Cholesterol			
If no chol then obtain			
Todays date			

Observation	Recording	Date next due	Signed
BP on arrival			
BP after 5 mins			
Weight in KG			
Height in cm			
If Smoker - amount			
Cholesterol			
If no chol then obtain			
Todays date			

Observation	Recording	Date next due	Signed
BP on arrival			
BP after 5 mins			
Weight in KG			
Height in cm			
If Smoker - amount			
Cholesterol			
If no chol then obtain			
Todays date			

Medication compliance

From the questionnaire does there appear to be compliance with medication: Yes/No

If there appears to be non compliance, what appears to be the problem:

Doesn't know which tablets to take	
Takes too many tablets	
Doesn't collect prescriptions	
Doesn't take any tablets	
Takes only some of prescribed tablets	
Other, please state	

Alcohol

State answer from the questionnaire :

Does there appear to be a problem : Yes/No

Smoking

Do you smoke : Yes/No

If no, have you ever smoked : Yes/No

How many do you smoke a day =

What type of cigarettes do you smoke:

Low Tar	
Medium Tar	
Normal Tar	
Extra Strong	
Cigars	
If Cigars, do you inhale	

1 In general, would you say your health is

- ☐ excellent ☐ very good ☐ good ☐ fair ☐ poor

2 Compared to a year ago, how would you rate your health in general now

- ☐ Much better now than one year ago
☐ Somewhat better than a year ago
☐ About the same
☐ Somewhat worse than a year ago
☐ Much worse than one year ago

3 The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much?

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a) Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports			
b) Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf			
c) Lifting or carrying groceries			
d) Climbing several flights of stairs			
e) Climbing one flight of stairs			
f) Bending, kneeling or stooping			
g) Walking more than a mile			
h) Walking half a mile			
i) Walking a 100 yards			
j) Bathing and dressing yourself			

4 During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Answer Yes or No to each question.

- a) Cut down on the amount of time you spent on work or other activities ☐ Yes ☐ No
- b) Accomplished less than you would like ☐ Yes ☐ No
- c) Were limited in the kind of work or other activities ☐ Yes ☐ No
- d) Had difficulty performing the work or other activities
(eg it took extra effort) ☐ Yes ☐ No

5 During the past 4 weeks, have you had any of the following problems with your work or other regular activities as a result of any emotional problems (such as feeling depressed or anxious)?

Answer Yes or No to each question.

- a) Cut down on the amount of time you spent on work or other activities ☐ Yes ☐ No
- b) Accomplished less than you would like ☐ Yes ☐ No
- c) Didn't do work or other activities as carefully as usual ☐ Yes ☐ No

6 During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups:

- ☐ Not at all ☐ Slightly ☐ Moderately ☐ Quite a bit ☐ Extremely

7 How much bodily pain have you had during the past 4 weeks?

- ☐ None ☐ Very mild ☐ Mild ☐ Moderate ☐ Severe ☐ Very

severe

8 During the past 4 weeks, how much did pain interfere with your normal work (including work both outside the home and housework)?

- ☐ Not at all ☐ A little bit ☐ Moderately ☐ Quite a bit ☐ Extremely

9 These questions are about how you feel and how things have been with you during the past month.
(For each question, please indicate the one answer that comes closest to the way you have been
feeling.)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
<u>How much time during the past month</u>						
a) did you feel full of life?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) have you been a very nervous person?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) have you felt so down in the dumps that nothing could cheer you up?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) have you felt calm and peaceful?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) did you have a lot of energy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) have you felt downhearted and low?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) did you feel worn out?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) have you been a happy person?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) did you feel tired?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) has your health limited your social activities (like visiting friends or close relatives)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

10 Please choose the answer that best describes how true or false each of the following statements is
for you.

	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
Please tick one box on each line					
a) I seem to get ill more easily than other people	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) I am as healthy as anybody I know	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) I expect my health to get worse	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) My health is excellent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Angina

Visual Analogue Scale

Zero represents no affect to overall health and well being

Seven represents complete disability, discomfort and restriction to life

Place a cross on the scale which represents your Anginal symptoms best

Angina $0 \bullet \bullet \bullet \bullet \bullet \bullet \bullet T$

Breathlessness 0 ●●●●●●●●

Place a cross on the scale which represents how well you manage your Anginal symptoms:

Angina 0 ● ● ● ● ● ● ● 7

Breathlessness 0 ● — ● — ● — ● — ● — ● — ● — 7

How often do you use your GTN sublingual sprayper day
.....per week

.....per week

What things tend to bring on your angina symptoms: circle all that apply

Exercise	Cold weather	Heavy meals
1. The temperature of the body is raised.		
2. The temperature of the body is lowered.		
3. The temperature of the body is not affected.		

Stress	Lying flat	Walking uphill
100%	75%	60%
80%	60%	45%
60%	45%	30%
40%	30%	15%
20%	15%	5%
0%	5%	0%

Other (please state)

Summary of assessment

Observations :

Medication compliance :

Alcohol :

Smoking :

Diet :

Exercise:

General Health :

Angina/Breathlessness :

Education on heart disease:

Brief evaluation of assessment :

ACTION PLAN

Suggestion	Discussed with GP	Date discussed	Action to be taken

Extracts from this questionnaire are taken from **The Short Form 36 Health Survey**
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Appendix IX: Patient held record cards

CORONARY HEART DISEASE
INTEGRATED CARE PROJECT

Name: _____

Address:

Date of Birth:

Please carry this card with you.

Nurse: KATY JOSS

Contact No: 0141 772 4744 (SMP)

0141 201 3000

page:4227 Stobhill Hospital



Stobhill NHS Trust, Cardiology Dept.
133 Balmorock Rd. Glasgow G 21 3UW
Tel: 0141 201 3058

Dr:

[illegible]

Appendix X: Abstract accepted for poster presentation at the European Society of Cardiology 2000, Amsterdam, The Netherlands 26-30 August 2000

SECONDARY PREVENTION OF CORONARY HEART DISEASE - AN INTEGRATED APPROACH

KA Joss; GM Lindsay; FG Dunn

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Introduction Recent studies have demonstrated that follow up and treatment for patients with Coronary Heart Disease (CHD) remains clearly deficient and that more effective methods of health promotion and education are required to reduce cardiovascular morbidity and mortality. The concept of hospital trained cardiac nurses in providing the link between primary and secondary care may be one way to integrate care in patients with CHD.

Method As part of a prospective intervention study being undertaken in the North of Glasgow, patients with CHD were identified and contacted. Patients were invited to the General Practice premises for a one to one assessment of risk factors and medical treatment. Advice was given regarding risk factor modification and appropriate changes to medical management initiated by the nurse specialist. Patients were followed up on a three monthly basis to monitor progress.

Results Complete data on Cholesterol, Systolic Blood Pressure (SBP), Body Mass Index (BMI) and Smoking was available for 59 patients, on entry to study and at three and nine months of follow up.

There was a progressive reduction in random serum cholesterol over the study period. Mean cholesterol at baseline, three and nine months being 5.6, 4.9 and 4.8mmol/l respectively. The percentage of patients with a random serum cholesterol of >5.0mmol/l was 71%(42/59), 40.6%(24/59) to 28.8%(17/59) over the same period.

SBP also reduced over the study period. Mean SBP being 138, 128 and 124mm/Hg respectively. The percentage of patients with a SBP >140mm/Hg was 37%(22/59), 16.9%(10/59) and 8.5%(5/59) over the same period.

BMI did not significantly change. Mean BMI being 27.54, 27.27 and 27.75 respectively. The percentage of patients with a BMI >30 was 27%(16/59), 23.7%(14/59) to 22%(13/59) over the same period.

The percentage of patients smoking was 22%(13/59), 22%(13/59) to 18.6%(11/59) over the same period with 8 reducing their smoking habit.

A paired 2 tailed t-test was used to compare results at baseline to nine months. BMI was not significantly different $p=0.47$. Smoking was significantly reduced $p=0.007$. The reduction in cholesterol and SBP was highly statistically significant $p<0.001$.

Conclusion The two major barriers to successful risk factor modification in General Practice are lack of time and specialist input. We have demonstrated that a Nurse Specialist integrating care between the Primary and Secondary interface does significantly improve risk factor modification in a group most likely to benefit from such intervention.

Appendix XI: Professional Nurse: Nurse-led interventions contribute to cutting the risks for heart disease

Professional Nurse

Nurse-led interventions contribute to cutting the risks for heart disease
VOL 18, NO 11, 01 July 2003

Katy Joss, RN, Cardiac Nurse Specialist, Stobhill Hospital, Glasgow; Grace **Lindsay**, BSc (Hons), RN, RM, MN, PhD, Reader in Clinical Nursing Research, Glasgow Caledonian University/North Glasgo University NHS Trust, Glasgow

Patients admitted to hospital with a coronary heart disease (CHD) event should be invited to participate in a multidisciplinary programme of secondary prevention and cardiac rehabilitation, as recommended in Standard 12 of the *National Service Framework for Coronary Heart Disease* (NSF) (DoH, 2000).

In addition, a large proportion of CHD patients who are managed in general practice and/or on a hospital outpatient basis and who may not have had the opportunity to attend formal cardiac rehabilitation programmes would benefit from appropriate secondary prevention. Cardiac rehabilitation programmes vary across the UK in terms of the patient groups who are eligible to join. Many limit access to post-myocardial infarction patients and post-coronary artery bypass patients only (Bethell et al, 2001; Thompson et al, 1997).

The aims of cardiac rehabilitation and secondary prevention measures are to reduce the risk of subsequent cardiac problems and promote a return to a full and normal life. This paper focuses on the impact of nurse-led initiatives in the provision of secondary preventive care for a range of patient groups with CHD.

A growing body of research-based evidence has shown in recent years that a range of interventions can lead to a reduction in the mortality of patients with CHD (SIGN, 2002).

Prophylactic medication

Aspirin has been shown to significantly reduce vascular events - vascular death, non-fatal stroke and myocardial infarction (MI) - by 13-42% in a range of patient groups who have suffered, or are at high risk of, vascular events (Antiplatelet Trialists' Collaboration, 1994; SIGN, 1999).

A meta-analysis of studies involving more than 20 000 patients on long-term beta-blocker therapy following an MI showed a 23% reduction on all-cause mortality and a 32% reduction in sudden death (Held and Yusuf, 1993).

Ace inhibitors In addition to aspirin, long-term angiotensin-converting-enzyme (ACE) inhibitors should be considered for patients following MI with or without left ventricular dysfunction (HOPE, 2001).

CHD risk-factor reduction

Treatment to target major CHD risk factors, namely hypertension (BP >140/90mmHg) (Browner and Hulley, 1989) and hyperlipidaemia (total cholesterol >5mmol/L) (Scandinavian Simvastatin Survival Study Group, 1994; Heart Protection Study, 2002) has shown reductions in mortality of 30%. The promotion of healthy lifestyles - including smoking cessation (Cupples and McKnight, 1994; Wilhelmsson, 1988), having a diet high in fruit, vegetables, nuts, grains and fish oils (Burr et al, 1989; De Lorgeril et al, 1994; Moher, 1995), and, in obese patients, weight loss (Katzel et al, 1995) and increased physical exercise (Wenger, 1995) - can have a significant effect on the prevention of CHD events.

However, despite the evidence of the benefits of these changes in lifestyle they are not necessarily implemented in practice, and suboptimal treatment of CHD patients with prophylactic medications and achievement of risk factor targets have been reported (Brady, et al, 2001)

Nurse-led initiatives

There is growing evidence of the effectiveness of nurse-led secondary interventions for patients with CHD, particularly in primary care settings. The results of large-scale randomised controlled trials highlight principles of good practice.

Different approaches to the promotion of secondary prevention of CHD in primary care have been evaluated. The results of a large trial conducted in 21 GP practices that included 1906 CHD patients aged 55-75 years, reported a difference in the effectiveness of three different methods of promoting secondary prevention.

The methods included an audit of patients' medical notes, with feedback to the primary health-care team, compared with two groups with systematic recall to either GP follow-up or a nurse-led clinic (Moher et al, 2001). 'Adequate assessment' of serum cholesterol, blood pressure and smoking status was compared in terms of risk factors being recorded in the notes and follow-up assessment within a two-year period.

Adequate assessment of all three risk factors was much more common in the nurse and GP recall groups (85% and 76% respectively) than the audit group (52%). The systematic recall system for patients with CHD led to better patient assessment, although only small improvements in treatment or reduction in risk-factor levels were noted. After adjustment for baseline levels, the advantage of the nurse recall group, in terms of percentage of patients with appropriate management in smoking, cholesterol, blood pressure and antiplatelet medication, was 10% higher than the audit group and 8% higher compared with the GP recall group. It was noted in this study that nurses were good at taking patient histories but less good at exploring patients' perceptions and understanding of heart disease and medication (Moher et al, 2001).

In terms of the recommendations of the NSF for cardiac rehabilitation (DoH, 2000) this is an area where nurses should direct further attention. Other studies of nurse-led interventions in primary care have reported improved outcomes in terms of CHD risk-factor reduction and higher levels of prescription of prophylactic medication. A study involving 19 general practices (involving 1173 CHD patients) evaluated nurse-led CHD secondary prevention clinics where regular follow-up of patients (every two to six months) was undertaken compared with usual care (Campbell et al 1998a; Campbell et al 1998b).

The patients included in the study were less than 80 years old and had been prescribed nitrates, or were identified by computer or manual search of pre-existing morbidity and prescribing records with a diagnosis of CHD. For practical purposes, a random sample of patients was identified and recruited in order that numbers would be limited to 150 per practice. (This excluded just less than one-third of CHD patients identified and should be taken into account in any attempt to replicate this service for all CHD patients in general practice.)

The intervention and follow-up took place over one year. The clinics included a first visit lasting about 45 minutes and follow-up visits of about 30 minutes' duration, with the timing of follow-up determined by clinical circumstances but usually every two to six months. Clinic protocols were compiled by the primary care team, and training and education materials were available, together with client-held record cards.

The study concluded that nurse-led clinics improved medical secondary prevention outcomes (lowering blood pressure and cholesterol) and helped patients to make lifestyle modifications. The majority of patients gained at least one effective component of secondary prevention (for example, increasing exercise, cutting down on fatty foods and so on), although no effect on smoking cessation was achieved. Based on improvements in blood pressure and cholesterol levels, and a reduction in cardiac risk factors, it was estimated that a one-third reduction in cardiovascular events and mortality would be realised as a result of these changes.

A four-year follow-up of this cohort of patients has now been reported (Murchie et al, 2003). This shows significant improvements in the intervention group at one year (as reported above) except for smoking cessation, and the lifestyle changes were sustained for four years, except for the exercise. The control group, most of whom attended clinics after the first year, improved over the intervening years so that at the four-year follow-up there were no significant differences in treatment targets. There were more deaths in the control group (18.9%) compared with the intervention group (14.5%) over the mean follow-up period of 4.7 years. The authors conclude that nurse-led secondary prevention improved medical and lifestyle components of secondary prevention and this led to significant reductions in mortality over the medium term.

Specific high-risk CHD patient groups

For patients awaiting coronary artery bypass graft surgery, McHugh et al (2001) showed that a specialist nurse-led programme can improve coronary risk factors, anxiety and depression levels, and general health and well-being. Their randomised trial compared a specialist liaison nurse and practice nurse shared-care programme with standard care. The health needs of intervention group patients were assessed by a specialist cardiac liaison nurse to determine the content of a programme of monthly health education sessions. These were carried out alternately by the liaison nurse in patients' homes and by the practice nurse in the practice clinic.

Interventions addressing behavioural risk factors - smoking, physical inactivity, poor diet, and excess alcohol - were based on an individual's readiness to change (Prochaska and DiClemente, 1984). Those receptive to making changes were encouraged to evaluate the positive and negative aspects of change.

Patients in the nurse-led programme were more likely to stop smoking (25% compared with 2%), reduce obesity (24.5% compared with 10.2%), show improvement in anxiety levels, report an increase in physical activity and to maintain better blood pressure control.

Although there was a significant reduction in cholesterol levels in the intervention group there was no significant difference between the groups in terms of the proportion of patients with cholesterol levels achieving target levels. This may relate to the fact that as yet nurses are unable to prescribe lipid-lowering therapy. Patients in the specialist nurse-led programme were in better general health at the point of surgery as measured by the self-completed SF-36 health and well-being assessment questionnaire (Ware et al, 1993). The liaison system between specialist cardiac nurses, practice nurses and health visitors in combination with the use of patient-held records in this programme, was reported to be beneficial in promoting continuity of care.

Another study, by Jolly et al (1999), compared care directed by a specialist cardiac liaison nurse with standard preventive interventions provided in secondary care to patients discharged from hospital after an acute episode of angina or MI. The liaison nurse's role was to provide an important link to facilitate communication between primary and secondary care settings rather than direct patient care.

In Jolly et al's study, the patients' practice nurse was informed of the timing of discharge and provided with a summary of important clinical information either by telephone or fax within 24 hours. Again, continuity between primary and secondary care for post-discharge CHD patients was shown to have improved; however, patients demonstrated no improvement in the main modifiable CHD risk factors and did not report improvement in quality of life.

Conclusion

Nurses have a key role in promoting cardiac rehabilitation and secondary prevention. A range of important principles for practice associated with improved outcomes in nurse-led initiatives for patients with CHD are set out in Box 1.

Since it is recognised that not all CHD patient groups will be offered a formal cardiac rehabilitation programme, and not all those invited to attend do so (Bethell et al, 2001), a wider range of approaches such as described in this paper should be considered in order that patients with established CHD are appropriately managed. Pivotal to the success of cardiac rehabilitation has been the multidisciplinary approach, ensuring good communication and education. The evidence supporting secondary prevention management of CHD is compelling and undoubtedly more investment in researching cardiac rehabilitation is required. Different models of cardiac rehabilitation exist and these at present predominate within secondary care. The way forward may be to shift the emphasis towards adopting integrated care pathways working across primary/secondary care.

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